FEDERAL REGISTER

Vol. 78 Friday,
No. 139 July 19, 2013

Pages 43061–43752

OFFICE OF THE FEDERAL REGISTER

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WHEN: Tuesday, September 17, 2013
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 950

[SATS No: WY–043–FOR; Docket ID: OSM–2012–0020; S1D1SSS08011000SXDO66 A0067F134S180110; S2D2SSS0801100 0SX066A00033F13XS501520]

Wyoming Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM), is removing previously disposed-of state program disapprovals and required program amendments for Wyoming that remain codified in the Code of Federal Regulations (CFR). The disapprovals and required program amendments are no longer necessary because Wyoming subsequently submitted and obtained OSM approval of revised regulations under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act).

DATES: Effective July 19, 2013.

FOR FURTHER INFORMATION CONTACT: Jeffrey Fleischman, Chief, Denver Field Division, Telephone: 307–261–6550, Internet address: *jfleischman@OSMRE.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion of Final Rule

At its own initiative (SATS number: WY–043–FOR, Administrative Record Docket ID No. OSM–2012–0020), OSM is removing certain Wyoming program disapprovals and required program amendments codified at 30 CFR 950.12 and 950.16 that have been previously addressed by the State and approved by OSM. A description of the disapprovals and required amendments being removed, including the citation and date of the original **Federal Register** document that resulted in their removal, are listed below in the order that they appear in 30 CFR 950.12 and 950.16.

A. Previously Addressed State Program Provisions That Were Not Approved

1. 30 CFR 950.12(a)(1)

The regulations at 30 CFR 950.12(a)(1) disapproved the phrases ''run-of-the-mine'' and ''to separate the coal from its impurities'' within the definition of ''coal preparation plant'' at Chapter I, section 2(m) of Wyoming's Coal Rules and Regulations. Wyoming subsequently deleted these phrases from its definition, and OSM approved their removal in a July 25, 1990, **Federal Register** (55 FR 30221, 30223).

2. 30 CFR 950.12(a)(3)

The regulations at 30 CFR 950.12(a)(3) disapproved the deletion of the requirement at Chapter II, section 3(a)(vi)(H)(II)(3) of Wyoming's Coal Rules and Regulations to collect baseline surface water data on acidity. Wyoming subsequently reinstated the requirement regarding surface water information at Chapter II, section 2(a)(vi)(L)(IV), and OSM approved it in a November 6, 2002, **Federal Register** (67 FR 67540–67541).

3. 30 CFR 950.12(a)(4)

The regulations at 30 CFR 950.12(a)(4) disapproved the deletion of the locational data requirements for monitoring stations at Chapter II, section 3(a)(vi)(M) of Wyoming's Coal Rules and Regulations. Wyoming subsequently explained that the requirements were present in its current rules at Chapter II, section 2(a)(vi)(J)(VIII), and OSM approved it in a November 6, 2002, **Federal Register** (67 FR 67540, 67543).

4. 30 CFR 950.12(a)(6)

The regulations at 30 CFR 950.12(a)(6) disapproved the replacement of the word ''is'' with the phrase ''the vegetative cover and total ground cover are'' in Chapter IV, section 2(d)(vi) of Wyoming's Coal Rules and Regulations. Wyoming subsequently deleted the reference to ''total ground cover'' and added the term ''absolute total'' to the phrase ''vegetative cover'' in Chapter IV, section 2(d)(ii)(B)(I), which is revised text from Chapter IV, section 2(d)(x) in the currently approved rules. OSM approved the deletion in a June 14, 2011, **Federal Register** (67 FR 34816, 34831).

5. 30 CFR 950.12(a)(7)

The regulations at 30 CFR 950.12(a)(7) disapproved the addition of the phrase ''or an alternative success standard approved by the Administrator'' to Chapter IV, section 2(d)(vi) of Wyoming's Coal Rules and Regulations. Wyoming subsequently deleted language in proposed Chapter IV, section 2(d)(i)(G) and 2(d)(ii)(B)(I), which is revised text from Chapter IV, section 2(d)(x) in the currently approved rules, that allows the use of unspecified alternative success standards when approved by the Administrator. OSM approved the deletion in a June 14, 2011, **Federal Register** (67 FR 34816, 34831).

6. 30 CFR 950.12(a)(10)

The regulations at 30 CFR 950.12(a)(10) disapproved all revisions to Chapter IV, section 3(a)(ix) of Wyoming's Coal Rules and Regulations concerning cut-and-fill terraces. Wyoming subsequently eliminated these revisions from its rules, and OSM approved their removal in a July 25, 1990, **Federal Register** (55 FR 30221, 30224).

7. 30 CFR 950.12(a)(11)

The regulations at 30 CFR 950.12(a)(11) disapproved the addition of section 1(a)(ii)(C), section 2(c), and section 3 to Chapter IX of Wyoming's Coal Rules and Regulations which would have provided a general variance from the approximate original contour requirements. Wyoming subsequently deleted the general variance provisions from its rules, and OSM approved their removal in a July 25, 1990, **Federal Register** (55 FR 30221–30222).

8. 30 CFR 950.12(b)

The regulations at 30 CFR 950.12(b) disapproved the addition of section 1(b)(iii) to Chapter XII of Wyoming's Coal Rules and Regulations which would have allowed personal property other than allowed by 30 CFR 800.5 (cash accounts, negotiable bonds, certificates of deposit, and letters of credit) to be posted as collateral bond. Wyoming subsequently revised its rules

in Chapter XII governing self-bonding to allow the use of personal property as collateral for securing self bonds. The revised rules addressed OSM's previously expressed concerns, and OSM approved them in a July 25, 1990, **Federal Register** (55 FR 30221, 30226–30227).

B. Previously Approved Required Program Amendments

1. 30 CFR 950.16(d)

The regulations at 30 CFR 950.16(d) required Wyoming to submit by September 24, 1990, a revision to its permanent program rules at Chapter IV, section 3(i) or otherwise propose to amend its program to require quarterly ground water monitoring for surface and underground coal mining operations. Wyoming subsequently amended its program as required, and OSM approved the changes in a November 6, 2002, **Federal Register** document (67 FR 67540, 67542).

2. 30 CFR 950.16(e)

The regulations at 30 CFR 950.16(e) required Wyoming to submit by September 24, 1990, a revision to its permanent program rules at Chapter IV, section 3(u) or otherwise propose to amend its program to give the State the authority to require additional preventive, remedial, or monitoring measures to assure that material damage to the hydrologic balance outside the permit area is prevented for both surface and underground coal mining operations. Wyoming subsequently amended its program as required, and OSM approved the changes in a November 6, 2002, **Federal Register** (67 FR 67540–67541).

3. 30 CFR 950.16(h)

The regulations at 30 CFR 950.16(h) required Wyoming to submit by June 30, 1987, revisions of the Land Quality Division (LQD) rules at Chapter II section 3(a)(vi)(J)(II) or otherwise propose to amend its program to provide that the groundwater quality description in a permit application must include pH. Wyoming subsequently amended its program as required at Chapter II section 2(a)(vi)(M)(III)(4), and OSM approved the changes in a November 6, 2002, **Federal Register** document (67 FR 67540–67541).

4. 30 CFR 950.16(i)

The regulations at 30 CFR 950.16(i) required Wyoming to submit by June 30, 1987, revisions to the LQD rules at Chapter II section 3(b)(ix)(D) or otherwise propose to amend its program to specify the minimum groundwater quality parameters that must be monitored. Wyoming subsequently submitted an amendment clarifying that the required minimum groundwater quality parameters were present in its current rules at Chapter IV, section 2(i), and OSM approved the changes in a November 6, 2002, **Federal Register** document (67 FR 67540, 67542).

Based on the information presented above, we are removing previously disposed-of state program disapprovals for Wyoming that remain codified at 30 CFR 950.12(a)(1), (3), (4), (6), (7), (10), (11), and (b) in this final rule. Additionally, we are removing previously disposed-of required program amendments for Wyoming at 30 CFR Part 950.16(d), (e), (h), and (i). Removal of these state program disapprovals and required program amendments does not alter the terms of our previous decisions or Wyoming's existing regulatory requirements.

II. Procedural Determinations

Administrative Procedure Act

We are publishing this final rule without prior public notice or opportunity for public comment. The Administrative Procedure Act (APA), 5 U.S.C. 553, provides an exception to notice and comment requirements when an agency finds that there is good cause for dispensing with notice and comment procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that, under 5 U.S.C. 553(b)(3)(B), good cause exists for dispensing with the notice of proposed rulemaking and public comment procedures for this rule.

Specifically, we have determined that notice and comment is unnecessary for this rule because it is nonsubstantive. As discussed above, this rule removes provisions concerning previously disposed-of state program disapprovals and required program amendments for Wyoming that remain codified at 30 CFR 950.12 and 950.16, respectively. This rule neither imposes new regulatory requirements nor removes any existing regulatory requirements.

For the same reasons, we find that good cause exists under 5 U.S.C. 553(d)(3) to have the regulation become effective on a date that is less than 30 days after the date of publication in the **Federal Register**.

Executive Order 12866

This rule is not a significant rule and is not subject to review by the Office of Management and Budget under Executive Order 12866. As discussed above, this rule removes provisions concerning previously disposed-of state program disapprovals and required program amendments for Wyoming that remain codified at 30 CFR 950.12 and 950.16, respectively. This rule neither imposes new regulatory requirements nor removes any existing regulatory requirements. For these reasons, we find that:

(1) This rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency for the reasons stated above.

(3) This rule does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

(4) This rule does not raise novel legal or policy issues for the reasons stated above.

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). As discussed above, this rule removes provisions concerning previously disposed-of state program disapprovals and required program amendments for Wyoming that remain codified at 30 CFR 950.12 and 950.16, respectively. This rule neither imposes new regulatory requirements nor removes any existing regulatory requirements.

Small Business Regulatory Enforcement Fairness Act

As discussed above, this rule removes provisions concerning previously disposed-of state program disapprovals and required program amendments for Wyoming that remain codified at 30 CFR 950.12 and 950.16, respectively. This rule neither imposes new regulatory requirements nor removes any existing regulatory requirements. Therefore, this rule is not considered a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act, and it will not—

(1) Have an annual effect on the economy of $100 million.

(2) Cause a major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regions because the rule does not impose new requirements on the coal mining industry or consumers.

(3) Have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on state, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on state, local, or tribal governments or the private sector. As discussed above, this rule removes provisions concerning previously disposed-of state program disapprovals and required program amendments for Wyoming that remain codified at 30 CFR 950.12 and 950.16, respectively. This rule neither imposes new regulatory requirements nor removes any existing regulatory requirements. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Federal Paperwork Reduction Act

This rule does not contain collections of information that require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

National Environmental Policy Act

This rule does not require an environmental assessment or environmental impact statement because section 702(d) of SMCRA, 30 U.S.C. 1292(d), provides that agency actions pertaining to approval of state regulatory programs do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Executive Order 12988 on Civil Justice Reform

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

Executive Order 13211 requires agencies to prepare a statement of energy effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule is not considered significant under Executive Order 12866, nor would it have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a statement of energy effects is not required.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on federally recognized Indian tribes and have determined that the removal of previously disposed-of state program disapprovals and required program amendments for Wyoming that remain codified at 30 CFR 950.12 and 950.16 would not have substantial direct effects on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

Executive Order 12630—Takings

Under the criteria in Executive Order 12630, this rule does not have significant takings implications; therefore, a takings implication assessment is not required. As discussed above, this rule removes provisions concerning previously disposed-of state program disapprovals and required program amendments for Wyoming that remain codified at 30 CFR 950.12 and 950.16, respectively. This rule neither imposes new regulatory requirements nor removes any existing regulatory requirements.

Executive Order 13132—Federalism

This rule does not have federalism implications. For the reasons previously stated, it will not have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554).

List of Subjects in 30 CFR Part 950

Intergovernmental relations, Surface mining, Underground mining.

Dated: June 10, 2013.

Allen D. Klein,

Director, Western Region.

For the reasons set out in the preamble, 30 CFR part 950 is amended as set forth below:

PART 950—WYOMING

■ 1. The authority citation for part 950 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Revised § 950.12 to read as follows:

§ 950.12 State program provisions and amendments not approved.

The following provisions of the Rules and Regulations of the Land Quality Division of the Wyoming Department of Environmental Quality are not approved:

(a) [Reserved]

(b) [Reserved]

§ 950.16 [Amended]

■ 3. In § 950.16, remove and reserve paragraphs (d), (e), (h), and (i) and remove reserved paragraphs (v) through (ll).

[FR Doc. 2013–17366 Filed 7–18–13; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG–2013–0542]

Drawbridge Operation Regulations; Arthur Kill, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulations governing the operation of the Arthur Kill AK Railroad Bridge across Arthur Kill, mile 11.6, between Staten Island, New York and Elizabeth, New Jersey. Under this temporary deviation the bridge may remain in the closed position for four days to facilitate scheduled maintenance. This deviation is necessary to facilitate tie and miter rail replacement on the lift span.

DATES: This deviation is effective from July 19, 2013 through July 31, 2013, and has been enforced with actual notice since July 17, 2013.

ADDRESSES: The docket for this deviation, [USCG–2013–0542] is available at *http://www.regulations.gov.*

Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call Joe Arca, Project Officer, First Coast Guard District, at (212) 668–7165, *joe.m.arca@uscg.mil.* If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The AK Railroad Bridge, across Arthur Kill, mile 11.6, between Staten Island, New York and Elizabeth, New Jersey has a vertical clearance in the closed position of 31 feet at MHW and 35 feet at MLW. The existing drawbridge operation regulations are listed at 33 CFR § 117.702.

The waterway supports both commercial and recreational navigation of various vessel sizes.

The operator of the bridge, Conrail, requested a temporary deviation to facilitate scheduled maintenance, tie and miter rail replacement at the bridge.

The bridge must remain in the closed position to perform this maintenance.

Under this temporary deviation the draw may remain in the closed position as follows:

On July 17, 2013 from 6:30 a.m. to 10:40 a.m. and from 12:50 p.m. to 4:40 p.m.

On July 18, 2013 from 7:30 a.m. to 11:35 a.m. and from 2:40 p.m. to 5:44 p.m.

On July 30, 2013 from 6:30 a.m. to 10:43 and from 12:43 p.m. to 4:35 p.m.

On July 31, 2013 from 7:30 a.m. to 11:35 a.m. and from 1:40 p.m. to 5 p.m.

There are no alternate routes for vessel traffic. The bridge can be opened in an emergency.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 8, 2013.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 2013–17321 Filed 7–18–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2013–0485]

RIN 1625–AA00

Safety Zone; Maritime Heritage Festival Fireworks, St. Helens, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone in St. Helens, OR. This safety zone is necessary to help ensure the safety of the maritime public during a planned fireworks display and will do so by prohibiting unauthorized persons and vessels from entering the safety zone unless authorized by the Sector Columbia River Captain of the Port or his designated representatives.

DATES: This rule is effective on July 27, 2013, from 9:45 p.m. until 10 p.m.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2013–0485]. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email ENS Ian McPhillips, Waterways Management Division, Marine Safety Unit Portland, U.S. Coast Guard; telephone (503) 240–9319, email *msupdxwwm@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because to do so would be impracticable considering the event will take place before the notice can be published or comments taken. Coast Guard Marine Safety Unit Portland did not receive the necessary information for this event until it was too late to issue an NPRM. Approximately 1,000 people are anticipating this event to commence as scheduled, and the event organizers are unable to reschedule the events in order to allow comment.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** because it is impracticable and contrary to the public interest. There is insufficient time remaining to undertake a 30 day delayed effective date for this rule.

B. Basis and Purpose

Fireworks displays create hazardous conditions for the maritime public due to loud noises, falling debris, and explosions, combined with the heavy vessel traffic congregating near the displays. The safety zone will help ensure the safety of the maritime public by prohibiting persons and vessels from risks associated with fireworks displays. As part of the Maritime Heritage Festival Fireworks in St. Helens, OR, the festival will feature a fireworks display. The Coast Guard expects approximately 1,000 people to attend this event. Because of the aforementioned concerns, the Coast Guard is establishing a safety zone in the vicinity of the launch site.

C. Discussion of the Final Rule

The rule establishes a safety zone in the Sector Columbia River Captain of the Port Zone.

The safety zone will be established on the Columbia River, St. Helens, OR. The safety zone will extend 500 yards in all directions from Sand Island marine Park. This event will take place on Saturday July 27, 2013 from 9:45 p.m. to 10 p.m.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and

executive orders related to rulemaking. Below we summarize our analyses based on these statutes and executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. The Coast Guard has made this determination based on the fact that the safety zone created by this rule will not significantly affect the maritime public because vessels may still coordinate their transit in the vicinity of the safety zone with the Coast Guard.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: the owners and operators of vessels intending to operate in the area covered by the safety zone on Saturday July 27, 2013, from 9:45 p.m. to 10 p.m.

The safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: (i) The safety zone is limited in size; (ii) the official on-scene patrol may authorize access to the safety zone; (iii) the safety zone will affect a limited geographical location for a limited time; and (iv) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the creation of a safety zone around a fireworks display. This rule is categorically excluded from further review under paragraph 34(g) of Figure

2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–253 to read as follows:

§ 165.T13–253 Maritime Heritage Festival, St. Helens, Oregon.

(a) *Safety Zone.* The following areas are designated safety zone:

(1) *Location.* All waters of the Columbia River at St. Helens, OR encompassing a 500 yard radius in all directions from the discharge site.

(2) *Enforcement period.* This safety zone is in effect from Saturday July 27, 2013, from 9:45 p.m. to 10 p.m.

(b) *Regulations.* In accordance with the general regulations in 33 CFR part 165, subpart C, no person may enter or remain in the safety zone created in this section or bring, cause to be brought, or allow to remain in the safety zone created in this section any vehicle, vessel, or object unless authorized by the Captain of the Port or his designated representative. The Captain of the Port may be assisted by other Federal, State, or local agencies with the enforcement of the safety zone.

Dated: July 2, 2013.

B.C. Jones,

Captain, U.S. Coast Guard, Captain of the Port, Sector Columbia River.

[FR Doc. 2013–17311 Filed 7–18–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[Docket No. 0808041047–3587–03]

RIN 0648–AW62

Magnuson-Stevens Act Provisions; National Standard 2—Scientific Information

AGENCY: National Marine Fisheries Service (NMFS); National Oceanic and Atmospheric Administration (NOAA); Commerce.

ACTION: Final rule.

SUMMARY: This final action amends the guidelines for National Standard 2 (NS2) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) regarding scientific information. Consistent with the President's memo on Scientific Integrity (March 9, 2009) and NOAA Administrative Order 202–735D, the revised NS2 guidelines are intended to ensure the highest level of integrity and strengthen public confidence in the quality, validity and reliability of scientific information disseminated by the National Marine Fisheries Service (NMFS) in support of fishery management actions. This action provides guidance on what constitutes best scientific information available (BSIA) for the effective conservation and management of fisheries managed under Federal fishery management plans (FMPs), and adds new language to the NS2 guidelines regarding the advisory role of the Scientific and Statistical Committees (SSCs) of the Regional Fishery Management Councils (Councils) and the relationship of SSCs to the peer review process. The revised NS2 guidelines also clarify the content and purpose of the Stock Assessment and Fishery Evaluation (SAFE) Report and related documents. This action makes modest adjustments to current operating practices; it is intended to ensure that scientific information, including its collection and analysis, has been validated through peer review, as appropriate, is transparent to the public, and is used appropriately by SSCs, Councils, and NMFS in the conservation and management of marine fisheries.

DATES: Effective July 19, 2013.

ADDRESSES: Copies of supporting documents prepared for this final rule, such as the proposed rule and public comments that were received, can be found at the Federal e-Rulemaking portal: *http://www.regulations.gov* by searching for RIN 0648–AW62.

FOR FURTHER INFORMATION CONTACT: William Michaels by phone 301–427–8155, by FAX at 301–713–1875, or by email: *William.Michaels@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Overview of Revisions to the NS2 Guidelines

Section 301(a)(2) of the MSA specifies that fishery conservation and management measures shall be based upon the best scientific information available. 16 U.S.C. 1851(a)(2). Section 301(b) of the MSA states that: ''the Secretary (of Commerce) shall establish advisory guidelines (which shall not have the force and effect of law), based on national standards, to assist in the development of fishery management plans.'' *Id.* 16 U.S.C. 1851(b). The existing national standard guidelines appear at 50 CFR 600.305 through 600.355. In the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2007, Congress added provisions to improve the use of science in decision-making, including a stronger role for Councils' SSCs in the review of scientific information and providing fishing level recommendations to their Councils, and authorizing the Secretary and Councils to establish a peer review process for scientific information used to advise Councils about conservation and management of fisheries. These revised NS2 guidelines address the above changes in the MSA. The guidelines include guidance on what constitutes BSIA for fishery conservation and management measures, provide standards for scientific peer review, clarify the role of the SSC in the review of scientific information for its Council, expand and clarify the contents of SAFE reports, and emphasize the importance

of the availability and transparency of SAFE reports used in Council decision making.

We published an advanced notice of proposed rulemaking (ANPR) in the **Federal Register** on September 18, 2008 (73 FR 54132), announcing the agency's intent to revise the NS2 guidelines, and received public comments from 24 organizations providing recommendations. The proposed guideline revisions published in the **Federal Register** on December 11, 2009 (74 FR 65724), and were open for public comment for three months, through March 11, 2010. We received comments from 25 organizations and 118 identical email submissions. In general, the public comments were supportive of the need to revise the NS2 guidelines and provided informative recommendations and some editorial clarifications. We address changes made in the final NS2 guidelines in the next section (Section II), and summarize comments received on the proposed guidelines and respond to those comments in Section IV. Response to Comments.

II. Synopsis of Changes Made in the Final Action

This final action does not include substantive changes from the proposed guideline revisions. In response to public comments, changes were made to clarify the guidelines and emphasize the importance of public transparency in peer review of scientific information, as recommended by public comments. Language was added to clarify the following: Scientific information includes both established and emerging science; peer reviewers should not make formal fishing level recommendations, because this is the purview of the SSC; no individual can be appointed to a review panel if that individual has a conflict of interest that is relevant to the functions to be performed; peer reviews that require a greater degree of independence should use rotation of reviewers, recognizing that repeated service by the same reviewer may be unavoidable when there is a limited availability of expertise; SAFE reports should contain an explanation of information gaps and highlight needs for future scientific work; and for stocks managed cooperatively by Federal and State governments, the scientific information used for FMP development should include harvest information from both state and Federal waters. See Section V of this preamble for a detailed description of the changes made to the text of the proposed action.

III. Overview of the Major Aspects of the Final Action

A. Best Scientific Information Available (BSIA)

In 2004, the National Research Council (NRC) of the National Academies examined the application of the BSIA standard in the development of fishery conservation and management measures. The NRC recommended approaches to more uniformly apply the BSIA standards for fishery management actions. The NRC recommendations are available in the NRC (2004) publication entitled ''Improving the Use of the 'Best Scientific Information Available' Standard in Fisheries Management'' (2004, *http://books.nap.edu/openbook.php*).

The revised NS2 guidelines adopt, to the extent possible, the 2004 NRC recommendations regarding the production and use of scientific information for fishery management actions. The public comments provided a nearly unanimous recommendation that the NS2 guidelines should be revised to incorporate the NRC recommendations, and that an overly prescriptive definition of BSIA should be avoided due to the dynamic nature of science. Therefore, as recommended by the NRC, the NS2 guideline revisions are based on the following widely accepted criteria for evaluating BSIA: Relevance, inclusiveness, objectivity, transparency, timeliness, verification, validation, and peer review of fishery management information as appropriate. The revised NS2 guidelines do not prescribe a static definition of BSIA because science is a dynamic process involving continuous improvements.

The availability and quality of scientific information to inform fisheries management varies. Ecosystems and human societies are complex, interacting, dynamic systems that are impacted by multiple factors, including those within the scope of fisheries management. Some fisheries are well studied and have much information from long-term annual research surveys and comprehensive biological, social, and economic fisheries data collection programs. Other fisheries do not have the same breadth of information available. In light of this variability, the NS2 guideline revisions elevate the importance of evaluating the uncertainty and associated risk of the scientific information to inform fishery management decisions. The revised guidelines also provide that mandatory management decisions should not be delayed due to limitations in the scientific information or the promise of future data collection or analysis.

The NS2 guidelines provide guidance that is fundamental for the reliability and integrity of scientific information to be used by the Secretary and Councils to effectively manage and conserve our nation's living marine resources.

B. Peer Review Processes

Pursuant to its authority under the Information Quality Act (44 U.S.C. 3516), the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review (70 FR 2664, January 14, 2005) that establishes minimum peer review requirements for ''influential scientific information'' disseminated by Federal agencies. Section 302(g)(1)(E) of the MSA provides that: ''The Secretary and each Council may establish a peer review process for that Council for scientific information used to advise the Council about the conservation and management of the fishery.'' 16 U.S.C. 1852(g)(1)(E). If the Secretary and a Council establish such a process, it will be deemed to satisfy the requirements of the Information Quality Act, including the OMB Peer Review Bulletin guidelines. The revised NS2 guidelines provide guidance and widely-accepted national quality standards that should be followed to establish a peer review process per MSA section 302(g)(1)(E). They also provide flexibility to maintain existing peer review processes established by the Secretary and Councils, and clarify the role of the Councils' SSCs in the scientific review process.

MSA section 302(g)(1)(E) peer review processes must be carefully designed to maximize the likelihood of an outcome that is objective, and provide useful information relative to the intended scope of work. The revised NS2 guidelines adopt many of the OMB peer review standards, including balance in expertise, knowledge, and bias; lack of conflicts of interest; independence from the work being reviewed; and transparency of the peer review process. A peer review may take many forms, including individual letter or written review or panel reviews. Duplication of previously conducted peer review should be avoided. The amount of time and resources spent on any particular review and the degree of independence may depend on the novelty, controversy, and complexity of the scientific information being reviewed. Peer reviewers who are federal employees must comply with all applicable federal ethics requirements (available at: *http://www.oge.gov/*). Potential reviewers who are not Federal employees must be screened for conflicts of interest in accordance with

the procedures set forth in the NOAA Policy on Conflicts of Interest for Peer Review subject to OMB's Peer Review Bulletin (available at: *http://www.cio.noaa.gov/service_programs/NOAA_PRB_COI_Policy_110606.html*). The nature and scope of each peer review should be developed and defined prior to the selection of reviewers, to ensure that reviewers with the appropriate expertise and skills are selected.

Peer review processes established by the Secretary and a Council for that Council should not be duplicative and should focus on reviewing information that has not already undergone rigorous peer review. When the Secretary and a Council develop a peer review process per MSA section 302(g)(1)(E), the revised NS2 guidelines provide that they must publish a notice and brief description of the process in the **Federal Register**, make a complete, detailed description of the process publicly available on the Council's Web site, and update it as necessary.

The revised NS2 guidelines are not intended to replace or result in the duplication of effective peer review processes that have already been established by NMFS and the Councils, such as the Stock Assessment Workshop/Stock Assessment Review Committee (SAW/SARC), Southeast Data Assessment Review (SEDAR), Stock Assessment Review (STAR), and Western Pacific Stock Assessment Review (WPSAR). Section 302(g)(1)(E) of the MSA provides that the peer review process established by the Secretary and a Council may include existing committees or panels. The aforementioned existing peer review processes (SAW/SARC, SEDAR, STAR and WPSAR) may qualify as MSA section 302(g)(1)(E) review processes, if the determination is made by the Secretary in conjunction with the relevant Councils. If such a determination is made, the Secretary will announce the decision in the **Federal Register**.

The impact of this action on current Council peer review practices should be minimal because the peer review standards are consistent with OMB's policy and presently incorporated in the existing peer review processes established by the Secretary and Councils. However, it may be necessary to refine those existing review processes in accordance with these revised NS2 guidelines.

C. The Role of the SSC in the Review of Scientific Information

The NS2 guidelines address several roles of the SSC and/or SSC members: The SSC as scientific advisor to its Council; the SSC as a peer review panel; and SSC members' participation on other peer review panels. With regard to the advisory role, the NS2 guidelines provide that the SSCs are the scientific advisory bodies to the Councils.

Section 302(g)(1)(A) of the MSA mandates that: ''Each Council shall establish, maintain, and appoint the members of a scientific and statistical committee to assist it in the development, collection, evaluation, and peer review of such statistical, biological, economic, social, and other scientific information as is relevant to such Council's development and amendment of any fishery management plan.'' 16 U.S.C. 1852(g)(1)(A). As stated in MSA section 302(g)(1)(B), each SSC: ''Shall provide its Council ongoing scientific advice for fishery management decisions, including recommendations for acceptable biological catch, preventing overfishing, maximum sustainable yield, and achieving rebuilding targets, and reports on stock status and health, bycatch, habitat status, social and economic impacts of management measures, and sustainability of fishing practices.'' *Id.* 16 U.S.C. 1852(g)(1)(B).

Paragraph (c)(6) of the final action, which is substantively unchanged from the proposed action, clarifies that the SSC, and not a peer review process, provides recommendations to a Council for developing annual catch limits (ACLs). MSA section 302(h)(6) states that: ''Each Council shall . . . develop annual catch limits for each of its managed fisheries that may not exceed the fishing level recommendations of its scientific and statistical committee or the peer review process established under subsection (g).'' 16 U.S.C. 1852(h)(6). A possible interpretation of this section is that a Council could not exceed the fishing level recommendation of either the SSC or optional peer review process established under MSA section 302(g)(1)(E); if both provided recommendations, the lower of the two levels would be the limit. However, section 302(g)(1)(B) requires that each SSC: ''Shall provide its Council ongoing scientific advice for fishery management decisions, including recommendations for acceptable biological catch, preventing overfishing, maximum sustainable yield and achieving rebuilding targets . . .'' The SSC's acceptable biological catch (ABC) recommendation is the fishing level recommendation that is most relevant for developing an ACL.

As explained in the proposed action, NMFS believes that, when read in conjunction with MSA section 302(g)(1)(A)–(B), MSA section 302(h)(6) does not mean that a peer review process displaces the SSC's role in providing fishing level recommendations and other advice to its Council. A better reading of the two subsections is that they allow for development of fishing level recommendations either through the SSC or a peer review process, but ultimately, it is the SSC that provides final scientific advice to its Council. The purpose of a peer review process is to ensure the quality and credibility of scientific information, rather than directly providing scientific advice to a Council.

As reflected in § 600.315(b)(1)(ii) of the revised NS2 guidelines, a peer review process per MSA section 302(g)(1)(E) should be conducted early in the scientific evaluation process, in order to provide the SSC with a reasonable opportunity to review the peer review report and make recommendations to the Council. Section 600.315(c)(5) states that the SSC may provide a recommendation to its Council that is inconsistent with the findings of a peer review, in whole or in part, but in such cases the SSC should prepare a report outlining the areas of disagreement and the rationale and information supporting the SSC's determination. The revised NS2 guidelines also state that the SSC evaluation of peer review findings should be complementary to the overall scientific review process for the purpose of providing advice to its Council, and the SSC should not repeat a previously conducted technical peer review.

The revised NS2 guidelines state that an SSC member may participate in a peer review established pursuant to MSA section 302(g)(1)(E) when beneficial due to the expertise and regional knowledge of the SSC member, or when such participation would assist the SSC as a whole in its advisory role to the Council. If the SSC as a body or individual members of an SSC participate in a peer review established pursuant to MSA section 302(g)(1)(E), the SSC member(s) must meet the peer reviewer selection criteria as described in paragraph (b)(2) of the guidelines. For an SSC member or the SSC as a body to participate in a peer review, the guidelines require screening the SSC member(s) for conflicts of interest pursuant to NOAA's Policy on Conflicts of Interest for Peer Reviews Subject to OMB's Peer Review Bulletin. That policy prevents review of one's own work. Furthermore, the NS2 guidelines provide that the review and evaluation of scientific information by the Councils' SSCs should be transparent,

and should include the recording of minority viewpoints.

Some public comments focused on the evaluation and recommendations of the SSCs on the scientific information for catch-level specifications and pertinent measures of uncertainty. These issues were addressed in the MSA National Standard 1 (NS1) guidelines (74 FR 3178, January 16, 2009), and may be further refined in a subsequent update of the NS1 guidelines. (See 77 FR 26238, May 3, 2012.)

D. Stock Assessment and Fishery Evaluation (SAFE) Reports

The Secretary of Commerce (Secretary) has the responsibility for preparation and review of SAFE reports. The current NS2 guidelines state that the SAFE report is a document or set of documents that provides the Secretary and Councils with a summary of scientific information. The existing guidelines also contain specifications on the contents of SAFE reports. The revised NS2 guidelines provide further clarification on the purpose and content of the SAFE report. Specifically, they provide guidance on the scientific information that should be included in the SAFE report to enable the SSC to fulfill its role in providing its Council with ongoing scientific advice for fishery management decisions.

Some comments suggested that a SAFE report should be a single report; however the revised NS2 guidelines maintain the language from the previous NS2 guidelines that describes the SAFE report as a document or set of documents. This is necessary to provide the Secretary flexibility in the preparation of the SAFE report and accommodates differing regional practices with regard to the SAFE report. The revised NS2 guidelines clarify that the SAFE report should include essential fish habitat (EFH) information, in accordance with the EFH provisions contained in § 600.815(a)(10), as a stand-alone chapter or clearly noted section.

The revised NS2 guidelines contain provisions intended to facilitate the use of information in the SAFE reports and its availability to the Councils, NMFS, and public. For example, the NS2 guideline revisions specify, as recommended by public comments, that SAFE reports or similar documents must be made available by the Council or NMFS on a Web site accessible to the public, and that they include a summary of the information they contain and an index or table of contents of each component that comprises the SAFE report.

E. Fishery Management Plan (FMP) Development

This final action maintains the current NS2 guidelines language on FMP development, with only minor changes to the organization of the text.

IV. Responses to Comments

NMFS received comments from constituents, regional fishery management councils and the general public on the proposed guideline revisions, and most of the commenters were supportive of the standards proposed for using the best scientific information available and having robust peer review processes. Commenters provided useful recommendations that were carefully considered during development of the final NS2 guidelines.

BSIA Criteria

Comment 1: One commenter stated that the proposed guidelines were lengthy, detailed, and prescriptive regarding what constitutes BSIA and how BSIA should be used. The commenter stated that this prescriptiveness may lead Councils and SSCs to conform to inappropriate or overly restrictive approaches, or open the door to legal challenge based on procedural technicalities.

Response: NMFS disagrees. The revised NS2 guidelines are advisory guidelines that do not have the force and effect of law. In the revised guidelines, NMFS adopted the NRC (2004) recommendations on what constitutes BSIA for improving fisheries management. Most commenters supported the inclusion of language outlining appropriate criteria of relevance, inclusiveness, objectivity, transparency and openness, timeliness, verification and validation, and peer review for evaluating BSIA. Furthermore, the guidelines are consistent with the Information Quality Act and the OMB Peer Review Bulletin requirements for improving the integrity of scientific information. This action is not overly prescriptive and provides sufficient flexibility to adopt new scientific protocols for data collection and analysis; as stated in paragraph (a)(5): ''Science is a dynamic process, and new scientific findings constantly advance the state of knowledge.''

Comment 2: One commenter suggested including additional clarification regarding the difference between ''established'' and ''emergent'' science as described by the American Fisheries Society and the Estuarine Research Federation (AFS/ERF). Other comments requested clarification of the language in paragraph (a)(4): ''Scientific information includes, but is not limited to, factual input . . .''

Response: NMFS has added language in paragraph (a)(4) that clarifies the difference between ''established'' and ''emergent'' science. The AFS/ERF committee was established to consider what determines the best available science for natural resource policies and management, and its 2006 report (Fisheries 31(9):460–465) distinguished ''established'' science as scientific knowledge derived and verified through the scientific process that tends to be agreed upon without controversy. ''Emergent'' science was defined as relatively new knowledge that is still evolving and being verified, therefore, potentially controversial because it is open to debate. Therefore, paragraph (a)(4) was revised to emphasize that: ''Emergent science should be considered more thoroughly, and scientists should be attentive to effective communication of emerging science.''

Comment 3: Some commenters recommended changing the phrase ''best scientific information available'' to other phrases such as ''best data available,'' ''best scientific data possible'' or ''best scientific information possible,'' suggesting that the modifiers ''best'' and ''available'' might result in a precedence for referring to scientific guesses and poorly done science or disputes over scientific information used in management.

Response: NMFS disagrees because the phrase ''best scientific information available'' is taken directly from NS2 in the MSA. See 16 U.S.C. 301(a)(2).

Comment 4: One commenter suggested modifying paragraph (a)(1) as follows: ''Successful fishery management depends, in part, on the thorough analysis of this information, and the extent to which the information is applied for: (i) Evaluating the impact that conservation and management measures will have on living marine resources, essential fish habitat (EFH), marine ecosystems, fisheries participants, fishing communities, and the nation; (ii) Identifying areas where additional management measures are needed; and (iii) Evaluating the consequences of not taking management actions when and where necessary.''

Response: NMFS agrees to add the language as recommended in (i) and (ii) which conveys important considerations for the success of fishery management. However, the suggested language for (iii) is not accepted because section 302(h) of the MSA requires Councils to prepare an FMP or amendments thereto for each fishery under its authority in need of

conservation and management. Therefore, not taking management action when and where necessary is not an option.

Comment 5: Commenters requested that the revised NS2 guidelines add environmental conditions (e.g., weather modeling) to the types of scientific data considered in marine conservation and management, and should specify that historical information shall include the use of weather (e.g., wind, air temperature, water temperature, and wave height data) and economic conditions (e.g., fuel prices) as all of these have tremendous effect on the fishery participation and effort estimates.

Response: NMFS agrees that environmental information is potentially useful for fisheries management. Ecological information mentioned in paragraph (a)(1) includes interactions of species with their environment, including the physical environment. The guidelines avoid being too prescriptive by not providing an exhaustive list of potential types of scientific information. The term ''environmental'' was inserted into the following sentence to be more inclusive: ''Fishery conservation and management require high quality and timely biological, ecological, environmental, economic, and sociological scientific information to effectively conserve and manage living marine resources.'' 50 CFR 600.315(a)(1).

Comment 6: Two commenters noted that there is no consideration of how the BSIA principles enshrined in the MSA should be applied to NMFS in pursuit of its responsibilities under the Endangered Species Act (ESA) or the Marine Mammal Protection Act (MMPA), and the NS2 guidelines should also specify that criteria for BSIA and peer review standards should be applicable to these other statutes.

Response: The National Standards and associated guidelines are specific to fishery management measures developed and promulgated under the MSA. The ESA and MMPA are separate laws with their own implementing regulations and science policies. Changes to those regulations and policies are beyond the scope of this action.

Comment 7: Some commenters suggested that the NS2 guidelines should provide more guidance for NMFS and Councils' SSCs to address the lack of scientific information, resolve critical data gaps, and specify that investments in time, effort, and funding are required to turn data poor fisheries into data rich fisheries. One commenter recommended that the NS2 guidelines include the statement: ''For fisheries that are data poor and require management, every effort should be made to collect data that will increase the certainty of needed management actions.'' Another commenter suggested that paragraph (a)(3) should state: ''In information-limited situations where simpler tools and assessment methods are warranted, scientific advice should be accompanied by recommendations for prioritizing data-needs in the short and long-term to move the fishery into a higher data category and improve assessment methods.'' One commenter also suggested adding, ''identification of future research areas and funding priorities'' to the end of the list of research-plan elements in paragraph (a)(5).

Response: NMFS did not add the suggested language because the revised guidelines adequately address the importance of the evaluation of uncertainty, identification of data gaps, and assessment of risks associated with limited information when developing fishery management actions. NMFS also believes that funding and priorities for resolving data gaps are best addressed by the peer review and research prioritization processes of the Secretary and Councils.

Comment 8: Some commenters expressed concern about the evaluation of uncertainty and data gaps in scientific information and the effect on SSC and Council decision-making. The commenters reported that their experience thus far indicates that a lack of information merely results in reduced quotas and fishing effort so as not to trigger the annual catch limit (ACL) or accountability measures (AM) thresholds pursuant to MSA requirements. Some recommended that the NS2 guidelines should provide guidance on how uncertainty should be addressed beyond the guidance that is provided in the proposed rule. One commenter recommended a more cautious interpretation of findings where uncertainty is high in order to ensure conservation of data-poor species and provide an incentive to collect the necessary information. Some commenters suggested adding language stating that sources of uncertainty must be considered and accounted for to the maximum extent possible.

Response: The revised NS2 guidelines have sufficient, but not overly prescriptive, language on the importance of addressing uncertainty in scientific information. For example, paragraph (a)(2), states: ''Scientific information that is used to inform decision making should include an evaluation of its uncertainty and identify gaps in the information.'' Further guidance for addressing uncertainty is covered in the NS1 guidelines. 50 CFR 600.310(f)(4) and (6).

Comment 9: One commenter suggested that the statement in paragraph (a)(2): ''Limitations in scientific information may not be used as a justification for delaying fishery management actions,'' presupposes that in the absence of information, management actions should be taken even if there may be compelling reasons for not taking action until more information is known. The commenter recommended that in such circumstances, the NS2 guidelines need to allow for evaluation of a no action alternative in the absence of scientific information and should assess the consequences of action versus no action.

Response: NMFS struck the sentence at issue in paragraph (a)(2) because the concept of not delaying management actions due to limitations in scientific information is adequately addressed in paragraph (a)(6)(v). In response to the comment, the NS1 guidelines identify the need for a precautionary management response in the face of uncertainty, and the lack of data generally suggests the need for more precaution, but not inaction.

Comment 10: One commenter recommended that the NS2 guidelines establish a conservative precautionary default for each FMP in case of delays or problems with scientific information. Specifically, the more dated the scientific information used to support fishery management actions, the more caution should be used in setting the acceptable biological catch (ABC) level when there is uncertainty. NMFS should require the SSCs and Councils to be more conservative in their management decisions and to err on the side of precaution to reduce the risk of overfishing. If a Council delays management action, NMFS must step in and implement this precautionary default.

Response: It is beyond the scope of the NS2 guidelines to address the level of precaution needed to manage fisheries resources. The NS1 guidelines address the need for precaution, including a requirement that scientific uncertainty be taken into account when the SSC makes recommendations to its Council regarding acceptable biological catch (ABC) levels. The role of the NS2 guidelines is to assure that uncertainty is calculated as accurately as possible so that it can be taken into account consistent with the NS1 guidelines.

Comment 11: One commenter recommended an increased focus on economic impacts on coastal

communities in all fishery management decisions, and greater transparency as to how the various factors, including economic considerations, are weighted.

Response: National Standard 8 requires consideration of impacts on fishing communities when developing fishery conservation and management measures. The NS2 guidelines emphasize the importance of high quality and timely social and economic information for evaluating the impact that conservation and management measures will have on fishing communities, as well as living marine resources, essential fish habitat, marine ecosystems, fisheries participants and the nation.

Comment 12: One commenter, noting the increasing complexity of fisheries models, both for stock assessment and for social and economic analyses, recommended adding language in paragraph (a)(4) to reflect that system complexity will inevitably lead to more complex decision making models, especially in ecosystem based management, where stock assessments, social impacts and environmental systems are integrated into a single model or series of inter-connected models.

Response: Although efforts to take into account the full complexity of ecosystems and fisheries may lead to complex models, NMFS disagrees that this would inevitably lead to complex decisions. A range of model complexities, commensurate with data availability and management questions, is anticipated by NMFS to meet the needs of the Councils.

Comment 13: One commenter recommended directing fishery managers to use scientific information at the ecosystem level.

Response: Paragraph (a)(6)(i) of the revised NS2 guidelines directs that an important criteria for evaluating BSIA is its relevance to the current questions or issues under consideration. Thus, the guidelines provide that if it is appropriate for ecosystem level scientific information to be considered or included in a particular analysis, managers should consider such information. Further guidelines are not necessary.

Comment 14: One suggestion was provided to change the term ''data-poor'' to ''information-limited'' because even data-rich fisheries can be information-limited and require the use of proxies if certain crucial data are missing or highly uncertain.

Response: NMFS agrees and added the term ''information-limited'' to paragraph (a)(3) of the revised NS2 guidelines.

Comment 15: One commenter requested clarifying the use of ''surveys or sampling programs'' to determine if this includes only underwater sampling and fishing catch collections, or whether ''survey'' also includes non-scientific telephone and dockside questionnaires. The commenter recommended discontinuing the use of phone surveys and instead using information from fishing license applications and species endorsements.

Response: NMFS uses a range of surveys and sampling programs, including phone surveys, to collect scientific data from commercial and recreational fisheries. NMFS surveys that directly gather information from the public or business entities, including phone surveys administered by the NMFS Marine Recreational Information Program, have been reviewed and meet the rigorous OMB standards for survey methodologies employed by the Federal government. See OMB Guidance on Agency Survey and Statistical Information Collections (January 20, 2006).

Comment 16: One commenter questioned using peer review as a criteria for evaluating what constitutes BSIA, stating that external peer review, outside the normal SSC process, should not be a separate and mandatory criteria for determining BSIA, particularly because the use of peer review is discretionary in MSA section 302(g)(1)(E). The commenter recommended that external peer review should be an optional tool, best used in circumstances of significant controversy regarding scientific information. Another commenter recommended changing: ''. . . peer review, as appropriate; and communication of findings'' in paragraph (a)(5) to: ''shall include peer review; and subsequent communication of findings.''

Response: Paragraph (a)(6) of the revised NS2 guidelines does not mandate peer review in all cases, but simply lists peer review as one of many criteria for evaluating BSIA, to be used as appropriate. We believe the guidelines should be flexible, therefore paragraph (a)(5) calls for peer review ''as appropriate'' as an element of a sound research plan. The revised NS2 guidelines state that the Secretary and Council have discretion to establish a peer review process as provided in section 302(g)(1)(E) of the MSA and that: ''peer review should be used when appropriate.''

Comment 17: Paragraph (a)(6) of the proposed guidelines stated that: ''Principles for evaluating best scientific information must be based on relevance, inclusiveness, objectivity, transparency and openness, timeliness, verification and validation, and peer review, as appropriate.'' One commenter suggested changing ''must'' to ''should.'' Another recommended eliminating ''as appropriate'' and requested that the SSC should consider peer reviewed scientific information above non-peer reviewed scientific information.

Response: NMFS changed the quoted sentence in the revised guidelines to: ''Criteria to consider when evaluating best scientific information available are relevance, inclusiveness, objectivity, transparency and openness, timeliness, verification and validation, and peer review, as appropriate.'' The criteria for evaluating BSIA were adopted from the recommendations of the NRC (2004) on the application of BSIA principles in the development of fishery conservation and management measures. In response to the comments above, the change in paragraph (a)(6) was made to emphasize that these are criteria or factors to be considered when evaluating BSIA, not mandatory elements that must be met in all cases.

Comment 18: One commenter objected to the use of a management strategy based on a proxy derived from another geographic area and different species to judge the responses of industry participants or business decisions, and recommended use of socio-economic data from the affected management area. Another commenter requested clarification on how the proxy, related species, and other geographical information could be used in modeling in data poor situations as specified in paragraph (a)(6)(i).

Response: The NS1 guidelines address the use of a proxy or indicator species for specifying maximum sustainable yield (MSY) in data-limited situations. See 50 CFR 600.310(e)(1)(iii) and (iv). Although the use of proxies is acknowledged as a useful tool in data limited situations, NMFS has revised in paragraph (a)(6)(i) the phrase ''powerful tool'' to ''may be a useful tool'' in the final NS2 guidelines to ensure proxies are not used unnecessarily.

Comment 19: Commenters supported consideration of relevant local and traditional knowledge (LTK) when evaluating scientific information to support fishery management actions, particularly in data limited situations and for fisheries in regions comprised of diverse indigenous communities with extensive traditional and local ecological knowledge. Commenters recommended specifying that collection of LTK must be consistent with appropriate scientific methods, undergo scientific review, and peer review, which may include indigenous

fishermen and hunters as well as researchers from other relevant disciplines to evaluate the sources and methods of recording LTK. They additionally suggested adding standards and procedures for incorporating LTK into the scientific process to increase Councils' confidence in its use.

Response: NMFS agrees that using LTK in support of fishery management actions is important, and recognizes that there are various ways that LTK can be utilized in the fishery management process, including experiential LTK knowledge from both indigenous and non-indigenous sources. NMFS encourages the development of scientific approaches to collection and evaluation of LTK, but does not believe the NS2 guidelines should prescribe appropriate collection and evaluation of LTK.

Comment 20: With respect to the language in paragraph (a)(6)(ii)(C): ''To the extent possible, an effort should be made to reconcile scientific information with local and traditional knowledge,'' commenters recommended removing ''reconcile'' because it implies that scientific information must be made consistent with LTK, or vice versa, if there is a discrepancy. The use of ''reconcile'' could be misconstrued to mean that scientific information needs to be reconciled to conform to LTK information. LTK should not be required to be validated by another form of science for it to be incorporated or factored into a decision.

Response: NMFS agrees and will remove ''reconcile'' to ensure that LTK information is acknowledged and evaluated along with other scientific information. NMFS agrees that reconciliation of LTK and other information should not be necessary for Councils to consider both types of information. Where the two types of information directly conflict and both have been validated through their respective review processes (SSC and LTK review subcommittee), the Councils should adopt an approach that takes account of the uncertainty inherent in this conflict.

Comment 21: One commenter requested that paragraph (a)(6)(iii) identify what constitutes ''non-scientific considerations'' and clearly define ''standards for objectivity'' for scientific information. The commenter suggested that the final NS2 guidelines should describe the process for establishing, documenting, and evaluating compliance with the standard of objectivity.

Response: NMFS agrees that the proposed rule language should be clarified and has revised paragraph (a)(6)(iii) to read: ''Objectivity. Scientific information should be accurate, with a known degree of precision, without addressable bias, and presented in an accurate, clear, complete, and balanced manner. Scientific processes should be free of undue nonscientific influences and considerations.'' Non-scientific considerations include activities that negate the attributes of scientific standards, such as verification, validation, and approval by scientific review, as indicated in the BSIA section of the guidelines.

Comment 22: Most commenters supported the importance of transparency as specified in the proposed guidelines, while some expressed concern that more public transparency was needed during the scientific peer review and fishery management meetings. One commenter stated the entire review process should be transparent and recommended paragraph (a)(6)(iv)(B) specify all rationale for excluding data from analysis must be clearly explained.

Response: The NS2 guidelines emphasize that vetting of scientific information should be open and public. Moreover, the guidelines are consistent with MSA section 302(i)(2)(A) which provides broad public and shareholder access to the Councils' fishery conservation and management process. See 16 U.S.C. 1852(i)(2)(A). No change was made regarding paragraph (a)(6)(iv)(B) because it already states that: ''Scientific information products . . . should explain any decisions to exclude data from analysis.''

Comment 23: Two commenters expressed concern that paragraph (a)(6)(iv) suggests that a researcher must allow general public comments on all phases of research design, collection, and analysis. Without technical expertise, the public could not provide constructive comments from an analytical perspective, and the requirement to allow public comment during each stage of the scientific process would be cumbersome and result in delay, inhibit the scientific process, or politicize the research itself. Another commenter recommended requiring public comment on reports of uncertainty, statistical error, data limitations, and decisions to exclude data from analyses.

Response: To address the concern, in paragraph (a)(6)(iv) NMFS struck the text: ''the public should have access to each stage in the development of scientific information,'' and revised the paragraph to read: ''Public comment should be solicited at appropriate times during the review of scientific information.'' The goal of these revised guidelines is to provide flexibility while emphasizing the importance of both public access to the scientific information used to support fishery management actions and public comment. Transparency of scientific data and analytical methods is a precondition for reproduction by others of the analyses of scientific information as noted in the verification section.

Comment 24: One comment suggested adding after paragraph (a)(6)(iv)(B) a new paragraph as follows: ''(C) The reports of the SSC shall contain an analysis of the certainty of the findings and shall clearly state a confidence factor in the validity of the information and analysis in the form of a percentage of the reliability of the information provided.''

Response: NMFS does not agree with prescribing that the SSC report uncertainty in a particular way. There are many ways to characterize uncertainty, and there is no way to predetermine a particular level of uncertainty. Transparency regarding uncertainty is adequately addressed in paragraph (a)(2) of the revised guidelines that states: ''Scientific information that is used to inform decision making should include an evaluation of its uncertainty and identify gaps in the information.''

Comment 25: One commenter requested that the Councils be required to provide adequate time in their decision-making process to have scientific information analyzed and subjected to appropriate review before it is used to inform fishery management decisions, and that NMFS and the Councils establish benchmark stock assessment peer reviews sufficiently far in advance of SSC review and recommendations to its Council. Another commenter suggested changing ''must be brought forward'' to ''may be brought forward'' in paragraph (a)(6)(v)(B) on timeliness.

Response: The timing of a Council's decision-making process is not within the scope of the NS2 guidelines. However, NMFS agrees with the second commenter and has changed the language in paragraph (a)(6)(v) to ''may be considered for use.''

Comment 26: One commenter recommended that paragraph (a)(6)(vi) regarding verification and validation be moved to the Peer Review portion of the guidelines in paragraph (b) because unrealistic demands for validation and verification could be misused to delay action under the guise of requiring more research to validate uncertain information. The commenter believes the methodological considerations with using verification and validation to

evaluate BSIA are better addressed as subordinate points in the peer review section.

Response: NMFS retains the verification and validation section in the BSIA portion of the guidelines because these are important requirements of science that should be undertaken regardless of whether the science is peer reviewed. Verification is used to document scientific data collection and analytical procedures and NMFS routinely publishes sampling procedures for all of its major survey programs. Validation is the requirement to test scientific methodology and is also routinely done independently of peer review. The peer review section focuses on standards for conducting a peer review, such as the form of the review or criteria for selection of reviewers. The terms of reference for a specific peer review can require reviewers to determine if the science has been validated and verified. Paragraph (a)(6)(v) explicitly addresses delay concerns by stating that: ''Management decisions should not be delayed due to limitations in the scientific information or the promise of future data collection or analysis.''

Comment 27: One commenter suggested editing paragraph (a)(6)(vi)(B) to state: ''. . . the accuracy and precision of the estimates are adequate.''

Response: NMFS revised paragraph (a)(6)(vi)(B) to include both ''accuracy and precision'' as important in estimates, and further clarified the importance of accuracy by adding: ''Models should be tested using simulated data from a population with known properties to evaluate how well the models estimate those characteristics and to correct for known bias to achieve accuracy.''

Comment 28: Paragraph (a)(6)(viii) of the proposed guidelines states: ''To the extent practicable, the scientific information that supports substantial fishery management alternatives considered by a Council should be peer reviewed.'' Some commenters noted that peer review addresses scientific issues. This language implies that the peer review could apply to policy matters, including fishery management decisions, thereby undermining the role of the Councils as primary policy making bodies. One commenter stated that the NS1 guidelines distinguish between the scientific process (determination of overfishing levels (OFL) and ABC) and the management process (determination of ACL, annual catch target, and management measures), and that both processes are interdependent and closely linked. Although the scientific peer review process is well established, commenters expressed concern that the management process does not currently undergo a similar review process. Another commenter recommended that the NS2 guidelines advise the use of management strategy evaluation (MSE) or alternative technology, to support the peer review of management alternatives. MSE, which involves evaluating the tradeoffs and performance of different management alternatives, is a type of management tool for evaluating management alternatives that produce feedback into the stock assessment process.

Response: To clarify that peer review pertains to scientific information, NMFS has revised paragraph (a)(6)(vii) to read: ''The scientific information that supports conservation and management measures considered by the Secretary or a Council should be peer reviewed, as appropriate.'' In regard to comments suggesting that management alternatives must be reviewed, the choice between management alternatives is a policy decision and is outside the scope of the NS2 guidelines. The intent is not to peer review the Council's management decisions, but rather to ensure, as required by NS2, that conservation and management measures are based on BSIA. To that end, paragraph (a)(6)(vi)(B) provides: ''The concept of validation using simulation testing should be used, to the extent possible, to evaluate how well a management strategy meets management objectives.''

Peer Review Standards

Comment 29: Many comments supported the inclusion of the current OMB peer review requirements in the NS2 guidance, as appropriate, and the establishment of peer review processes pursuant to MSA section 302(g)(1)(E). Some commenters requested changing the heading of paragraph (b) to ''Optional Peer Review'' so that the standards apply only to optional peer reviews. Some commenters requested further guidance on when an independent peer review should occur and expressed concern with an ''optional'' peer review because this could indicate that the Councils, SSCs and agency are disinterested in utilizing this process. Other comments requested more prescriptive language including how or when peer review should be conducted, and by whom, especially when there is significant controversy regarding the scientific information on which fishery management decisions will be based. One commenter emphasized that the NS2 guidelines should require that each Council, working with the Secretary, determine whether an optional external peer review process is warranted, whereas others opposed the implication that an external peer review may be necessary, stating: ''The Council has sole discretion to establish a supplemental peer review.''

Response: NMFS does not agree that the peer review section should be titled ''optional peer review.'' MSA section 302(g)(1)(E) and the revised NS2 guidelines adequately convey that this is an optional, not mandatory peer review process. The language in section 302(g)(1)(E) clearly states that: ''The Secretary and each Council *may* establish a peer review process for that Council. . .'' 16 U.S.C.1852(g)(1)(E) (emphasis added). Thus the Secretary and each Council have the discretion, working together, to establish a peer review process. Under the revised guidelines, the Secretary and Councils have the necessary flexibility to continue to use and improve their existing peer review processes. See response to Comment 36 for factors to consider when determining whether to conduct a peer review, and if so, the appropriate level of review.

Comment 30: Commenters asked for clarification on the SSC's role as an advisory body to the Council and the SSC's participation in a peer review process established pursuant to MSA section 302(g)(1)(E). Some commenters requested that paragraph (b) of the revised guidelines clarify that the SSC is the primary and final peer reviewer for scientific information. One commenter stated that MSA section 302(g)(1)(E) was specifically crafted to allow SSCs to function as the primary peer review panel and that the SSC peer review satisfies the Information Quality Act requirements. Another commenter opposed the use of external peer reviewers, and stated that MSA section 302(g)(1)(E) allows Councils to use their own SSC as an optional peer review process at the discretion of the Council. One commenter stated the guidance in paragraph (b) should be for use only when a Council decides to use an external peer review, and that additional peer reviews beyond the SSC would further lengthen the Council process and should be avoided. Contrary to this, other commenters stated the SSC should not participate in peer reviews, but rather all peer reviews should be independent and external to the SSC process.

Response: MSA section 302(g)(1)(E) gives the Secretary and Councils the discretion to establish a peer review as appropriate, and does not preclude Councils from using their SSCs for peer review. Paragraph (b) of the revised NS2

guidelines: ''provides guidance and standards that should be followed in order to establish a peer review process per [MSA] section 302(g)(1)(E).'' NMFS does not agree that MSA section 302(g)(1)(E) states that SSC peer review alone satisfies IQA requirements, but rather, that a peer review process established by the Secretary and a Council is deemed to satisfy IQA requirements. NMFS believes that further revision to the guidelines is unnecessary because they are consistent with the MSA and clearly provide that the SSC, as a body or its members, may participate in peer review. The guidelines are clear that this discretionary peer review process is not meant to supplant the role of the SSC.

Comment 31: A commenter requested that the agency clarify whether the Secretary has the authority to veto a decision by a Council to establish a peer review process pursuant to MSA section 302(g)(1)(E), or whether the Council may proceed as it deems appropriate subject to ultimate Secretarial review of the consistency of the FMP with the MSA. The commenter recommended the latter view as the appropriate policy.

Response: NMFS disagrees with the suggested interpretation of MSA section 302(g)(1)(E) because that section clearly states that: ''the Secretary and each Council may establish a peer review process for that Council. . .'' The establishment of a peer review process is a joint Secretary-Council activity. NMFS disagrees with the suggestion that the Council may proceed as it deems appropriate, subject to ultimate Secretarial review. It is important to note that joint Secretary-Council establishment of a peer review process does not supplant the Secretarial authority to review consistency of Council fishery management plans, amendments or other actions with the MSA and other applicable law.

Comment 32: Commenters requested further clarification on the text in paragraphs (b)(1), and (c)(4) regarding duplicating or repeating peer reviews. One commenter expressed concern that the paragraphs could potentially restrict the SSC re-evaluation of peer-review reports. Commenters stated that the guidelines should have flexibility to allow for additional analysis within any review process that is complementary and not duplicative.

Response: As discussed in response to comment 30, *supra,* paragraph (b) of the revised guidelines explicitly states that: ''A peer review process is not a substitute for an SSC and should work in conjunction with the SSC.'' Paragraph (c)(4) of the guidelines provides that the SSC evaluation of peer review findings should be complementary to the overall scientific review process for the purpose of providing advice to its Council, and the SSC should not repeat a previously conducted technical peer review because of disagreement with peer review findings. NMFS believes that these provisions allow for sufficient flexibility and therefore, no changes were made to paragraphs (b)(1), or (c)(4).

Comment 33: Commenters supported paragraph (b)(4) that specifies: ''The Secretary will announce the establishment of a peer review process under [MSA] section 302(g)(1)(E) in the **Federal Register** along with a brief description of the process'' while other commenters were concerned that the proposed guidelines do not acknowledge the existing stock assessment review processes (SAW/SARC, SEDAR, STAR and WPSAR) as being consistent with the MSA section 302(g)(1)(E) review process. Two commenters recommended that the Secretary clearly identify which existing Council committees or panels meet the NS2 guideline standards, in order to avoid confusion, prevent duplication and improve the ability of NMFS and the Councils to determine the appropriate type of peer review required for particular information.

Response: The revised guidelines are consistent with the language in MSA section 302(g)(1)(E) that a peer review process established by the Secretary and a Council may include existing committees or panels. However, as with all other processes, in order to be recognized formally as MSA 302(g)(1)(E) processes, the same process as described in (b)(4) of the revised guidelines must be followed, culminating in an announcement of the formal designation in the **Federal Register**. NMFS disagrees that such determinations are made only by the Secretary, thus the guidelines provide for a role for both the Secretary and the relevant Council in making MSA section 302(g)(1)(E) determinations.

Comment 34: One commenter criticized the language in paragraph (b)(1)(iii) of the revised guidelines arguing that policy considerations are in the purview of the Secretary and the Councils. Some commenters suggested that the decisions on all fishery management plans should be peer reviewed. Another commenter requested clarification on ''scientific'' and ''policy'' reviews and suggested distinguishing scientific uncertainty as a matter for scientific peer review and risk tolerance as a matter for policy peer review.

Response: NMFS agrees that clarification would be helpful and has revised paragraph (b)(1)(iii) to read: ''The scope of work may not request reviewers to provide advice on policy or regulatory issues (e.g., amount of precaution used in decision-making) which are within the purview of the Secretary and the Councils, or to make formal fishing level recommendations, which are within the purview of the SSC.''

Comment 35: Some commenters suggested that the scope of peer reviews should include all stages of the scientific process. One commenter suggested that the guidelines should require all data and science used by NMFS or the Councils be subjected to peer review before being used to inform management decisions.

Response: NMFS agrees that the scope of peer review should include all stages of the scientific process and has clarified in paragraph (b)(1)(iii) that the scope of peer reviews includes ''evaluation of the various stages of the science.'' NMFS disagrees that all data and science should be peer reviewed because such a requirement would be impractical, not required in all cases, and would cause significant delays in the fishery management process.

Comment 36: Some commenters requested more specificity regarding what types of scientific information must be peer reviewed. One commenter recommended that paragraph (b)(1)(i) be revised not simply to provide the Secretary and Council with discretion to determine appropriate peer review processes, but to require them to identify major products they receive and to establish criteria for determining the appropriate peer review for each. An SSC peer review or other independent form of review should occur when significant revisions are made to a benchmark assessment. Another commenter stated that all benchmark assessments should be subject to a formal external review, and the reviewers must be independent from the science to be reviewed, such as reviewers drawn from the Center for Independent Experts (CIE) or another comparable outside organization.

Response: NMFS believes the revised NS2 guidelines provide sufficient guidance as to the necessity of and appropriate scope of peer review in paragraph (a)(6)(vii). This guidance is adopted from and consistent with the OMB peer review requirements. For peer reviews requiring a greater degree of independence, such as benchmark assessments, the Secretary and Councils routinely use independent reviewers,

including reviewers who are selected through the CIE process.

Comment 37: Commenters supported peer reviews being conducted early in the process of producing scientific information. Some commenters suggested further guidance on the timing of peer review. Another commenter suggested that NMFS and the Councils must provide compelling justification for foregoing established peer review processes.

Response: NMFS understands the importance of and need for conducting timely peer review to ensure that peer review findings are available to an SSC and its Council. NMFS has revised paragraph (b)(1)(ii) of the guidelines to read: ''The peer review should, to the extent practicable, be conducted early in the process of producing scientific information or a work product so peer review reports are available for the SSC to consider in its evaluation of scientific information for its Council and the Secretary.''

Comment 38: Two commenters recommended that peer review should be a tool used to review the SSC's advice, while other commenters stated that the peer review process should be used to inform the Council's SSC.

Response: NMFS disagrees that peer review should be used to review the SSC's advice because, as explained in paragraph (a)(6)(vii) of the guidelines: ''Peer review is a process used to ensure that the quality and credibility of scientific information and scientific methods meet the standards of the scientific and technical community.'' Paragraph (c)(4) correctly states: ''peer review of scientific information used to advise the Council, including a peer review process established by the Secretary and the Council under [MSA] section 302(g)(1)(E), should be conducted early in the scientific evaluation process in order to provide the SSC with reasonable opportunity to consider the peer review report and make recommendations to the Council as required under [MSA] section 302(g)(1)(B).''

Comment 39: Paragraph (a)(6)(v)(B) of the proposed guidelines stated that: ''Management decisions should not be delayed due to data limitations or the promise of future data collection and analysis.'' One commenter suggested revising the text to make clear that peer reviews cannot be used to justify delay of management decisions either, especially if a stock is overfished or subject to overfishing.

Response: NMFS agrees that this is the intent of the text (which was moved to paragraph (a)(6)(v) of the revised guidelines) and revised it to clarify: ''Mandatory management actions should not be delayed due to limitations *i*n the scientific information or the promise of future data collection or analysis.'' NMFS also added new text in paragraph (b)(1)(ii) regarding timing of peer reviews. (See response to Comment 37 for explanation.)

Comment 40: A commenter suggested inserting additional text in paragraph (b)(1)(iii) providing that the scope of peer reviews should include findings and recommendations on missing information, future research, data collection, and improvements in methodologies and should also specify the type of expertise and balance of perspective for a review panel.

Response: Paragraph (b)(2)(i) states: ''Peer reviewers must be selected based on scientific expertise and experience relevant to the disciplines of subject matter to be reviewed. The group of reviewers that constitute the peer review should reflect a balance in perspectives, to the extent practicable, and should have sufficiently broad and diverse expertise to represent the range of relevant scientific and technical perspectives to complete the objectives of the peer review.'' Therefore, NMFS believes that the guidelines sufficiently address expertise and balance of perspective for peer review. NMFS has revised paragraph (b)(1)(iii) to clarify that the scope of work should allow reviewers to make recommendations regarding ''missing information, future research, data collection, and improvements in methodologies.''

Comment 41: One commenter suggested revising paragraph (b)(2) to state that peer reviewer selection should be guided by the scope of work which, according to paragraph (b)(1)(iii), should be determined before selecting reviewers.

Response: NMFS believes the final rule has sufficient language to address the commenter's concern. Section (b)(1)(iii) specifies: ''The scope of work or charge (sometimes called the terms of reference) of any peer review should be determined in advance of the selection of reviewers'' and paragraph (b)(2)(i) states: ''Peer reviewers must be selected based on scientific expertise and experience relevant to the disciplines of subject matter to be reviewed, including a balance in perspectives'' to ensure the peer reviewer selection is guided by the scope of work.

Comment 42: One commenter recommended that the ''group of reviewers'' that constitute the peer review have sufficiently broad and diverse expertise, and should also be representative of all sectors of the resource that are to be effected (e.g., commercial interests, charter operators, party/head boat operators, and recreational interests).

Response: NMFS disagrees that scientific peer review must include representatives of all sectors with an interest in the resource. Input from such sectors occurs through the Council advisory panels, not through scientific peer review. The revised guidelines are clear on the peer reviewer qualification requirements of scientific expertise and experience relevant to the disciplines of subject matter to be reviewed, including a balance in perspectives.

Comment 43: One commenter suggested that paragraph (b)(2)(i) on expertise and balance, when read with paragraph (a)(6)(iii) on objectivity, appears to establish a process requiring public hearings and testimony before a group with ''a balance in perspectives'' that is formed in order to review ''substantial fishery management alternatives.''

Response: Peer reviews may require a balance in expertise and perspectives to review science that encompasses various disciplines, but seeking that balance should not involve consideration of non-scientific issues. NMFS provided clarification to show this is not the intent by revising paragraph (a)(6)(vii) to read: ''the scientific information that supports conservation and management measures considered by the Secretary or a Council should be peer reviewed'' to differentiate between reviewing science products and management actions.

Comment 44: One commenter expressed concern with the NS2 guidelines requiring a ''balance of viewpoints'' because a single individual would never meet this standard. The commenter recommended that the guidelines be revised to ensure a balance in the quality, number of perspectives, and number of reviewers.

Response: The language in paragraph (b)(2)(i) is not in reference to a single peer reviewer as the commenter suggested, but rather, the peer review body as a whole. NMFS revised the paragraph to clarify this point, as indicated in the response to Comment 40.

Comment 45: One commenter criticized the present peer review system claiming that NMFS controls all aspects of the process and stated that there should be outside or independent review of science used in support of fishery management actions, including data collection and analysis. The commenter stated that peer reviewers are ''handpicked'' by NMFS in the SEDAR peer review process. Another commenter recommended that members

of the peer review should not include members of the SEDAR, SSC, Advisory Panel, and the Council, thus eliminating potential sources for conflicts of interest.

Response: The final NS2 guidelines provide sufficient guidance to ensure that reviewers meet peer review standards consistent with the OMB's Peer Review Bulletin and the National Academies Policy on Committee Composition and Balance and Conflicts of Interest by specifying in paragraph (b)(2) that: ''The selection of participants in a peer review should be based on expertise, independence, and a balance of viewpoints, and be free of conflicts of interest.'' Paragraph (c)(1) of the guidelines provides that: ''SSCs may conduct peer reviews or evaluate peer reviews to provide clear scientific advice to the Council'' consistent with MSA section 302(g)(1)(A). See 16 U.S.C. 1852(g)(1)(A). In regard to the comment on SEDAR reviews, the SEDAR reviews include external peer reviewers who are independently selected by a third party, the Center for Independent Experts, to meet rigorous peer review standards.

Comment 46: Comments were generally supportive of the requirement that peer reviewers must not have conflicts of interest and included suggestions for revising paragraph (b)(2)(ii). One commenter suggested that the phrases ''real or perceived conflict of interest'' and ''any financial or other interest'' may create ambiguity and the opportunity for inappropriate manipulation of the selection process. Another commenter recommended that the definition of conflicts of interest be further expanded to include advocacy conflict of interest or conflict of interest of a recipient of any consulting agreement, grant, or contract with NMFS. Another recommendation was to revise the text to be more specific about the conditions under which a conflict of interest is unavoidable such as when there is only one qualified reviewer available.

Response: In response to comments, NMFS revised paragraph (b)(2)(ii) to delete ''real or perceived,'' but retained ''any financial or other interest.'' NMFS also revised the text to specify: ''For reviews requiring highly specialized expertise, the limited availability of qualified reviewers might result in an exception when a conflict of interest is unavoidable; in this situation, the conflict must be promptly and publicly disclosed.'' Consulting arrangements, grants and contracts are included as potential conflicts of interest in paragraph (b)(2)(ii)(B). Advocacy activities are adequately addressed in the NOAA Conflict of Interest policy, which is incorporated by reference into the NS2 guidelines in paragraph (b)(2)(ii).

Comment 47: One commenter stated that the selection of peer reviewers should be based on expertise and qualifications exclusively. Thus, paragraph (b)(2)(iii) should be revised to eliminate ''should rotate'' and the presumption that past service on a peer review panel is a basis for exclusion from future service.

Response: The guidelines are clear on the importance of expertise and qualifications in the selection of peer reviewers, and the intent of the language on rotation of peer reviewers across the available pool of reviewers is to avoid a situation where a peer reviewer repeatedly reviews his or her scientific contributions from a previous review. Therefore, NMFS disagrees with the request to remove the language regarding rotating reviewers.

Comment 48: Commenters generally agreed that the names of reviewers must be made publicly available. However one commenter suggested the language in paragraph (b)(3), ''Names and organizational affiliations of reviewers should be publicly available prior to review'' should be revised because of a concern for interference in the selection of independent reviewers. Another commenter requested that the guidelines specify that the peer reviewer selection process be publicly transparent, including the rejection of a potential reviewer based on conflicts of interest.

Response: NMFS agrees that the peer review process should be as transparent as possible, including the public disclosure of the names and affiliations of the reviewers. However, NMFS agrees to remove the text ''prior to review'' to allow the option to withhold names of peer reviewers prior to review, when necessary. NMFS notes this practice is consistent with the OMB Peer Review Bulletin. NMFS disagrees with the suggestion of requiring public transparency of rejected potential reviewers because this is not required by the OMB peer review guidelines. Additionally, conflict of interest disclosure information for potential reviewers contains sensitive financial information that must be held in confidence.

Comment 49: Most commenters supported the requirement for transparency in the peer review process, but one commenter expressed concern that it is impractical for public participation in all peer reviews. For example, the public could not attend a peer review conducted as an external desk review where a report is sent by email to the reviewer. Another commenter suggested that the guidelines appear to preclude any individual review, such as a desk review, because the guidelines imply that a review panel meeting is the only acceptable peer review process.

Response: Paragraph (b)(1)(i) specifies: ''The Secretary and Council have discretion to determine the appropriate peer review process for a specific information product. A peer review can take many forms, including individual letter or written reviews, and panel reviews.'' Therefore, a review panel meeting is not the only acceptable peer review process under the revised NS2 guidelines. To ensure transparency of all types of peer reviews, NMFS revised paragraph (b)(3) to read: ''A transparent process is one that ensures background documents and reports from peer review are publicly available . . . and allows the public full and open access to peer review panel meetings.''

Comment 50: Some commenters requested that the guidelines specify that background documents be made publicly available 30 days prior to a peer review.

Response: NMFS believes that inclusion of a specified number of days would be overly prescriptive because there are various forms of peer review, some of which may require a more expedited timeline. We believe that the guidelines adequately emphasize the importance of timeliness and transparency in peer review.

Comment 51: One commenter suggested that the 14 day advanced notice of a peer review meeting specified in the action should be extended to provide a minimum of a 21 day notice period.

Response: In order to extend the advance notice, NMFS revised the language in paragraph (b)(3) to read as: ''public notice of the peer review panel meetings should be announced in the **Federal Register** with a minimum of 14 days, and with an aim of 21 days, before the review to allow public comments during meetings.''

Role of SSC in the Review of Scientific Information

Comment 52: NMFS received many comments regarding whether or not the SSC should participate in peer review. Some commenters argued that the peer review standards in the revised NS2 guidelines are unnecessary and inconsistent with the role of the SSC to function as the primary and final peer review for scientific information brought before the Council. One commenter requested that the NS2 guidelines be amended to specify that

the SSC functions as the primary peer review panel in all cases unless the Council decides otherwise, and that the SSC should not need to meet the conflict of interest standards in paragraph (b)(2) when conducting peer review. Contrary to this view, other commenters insisted that all peer reviews be independent and external of the SSC, and that SSC members should not participate in peer review. Many commenters expressed support for paragraph (c) on the advisory role of the SSC and participation of the SSC in peer review, and supported clarifying that the peer-review process complements, but does not replace, the role of the SSC to provide ongoing scientific advice to its Council for management decisions.

Response: A primary reason for revising the NS2 guidelines was to clarify the distinction between the advisory role of the SSC to its Council as specified in MSA section 302(g)(1)(B), 16 U.S.C. 1852(g)(1)(B), and the ability of the SSC to assist in peer review, as specified in MSA section 302(g)(1)(A), *id.* § 1852(g)(1)(A). NMFS carefully considered public comments received in response to the ANPR and proposed rule requesting clarification on the distinction between these provisions. The revised guidelines specify that peer review is separate from the SSC's subsequent activity to evaluate scientific information for the purpose of providing advice, such as fishing level recommendation, to its Council. The revisions are also consistent with MSA section 302(g)(1)(E) providing the Secretary and Councils with the discretion to establish a peer review process. NMFS disagrees with comments that the SSC may not assist in peer review, as we believe that view is contrary to the plain language of MSA section 302(g)(1)(A). The revised NS2 guidelines encourage SSC members to participate in a peer review when such participation is beneficial due to the expertise and institutional memory of that SSC member, or beneficial to the Council's advisory body by allowing that SSC member to make a more informed evaluation of scientific information for its Council. The revised guidelines also state that participation of an SSC member in a peer review should not impair the ability of that member to fulfill his or her responsibilities to the SSC. NMFS disagrees with the recommendation that SSC members be completely exempt from paragraph (b)(2) addressing peer reviewer selection, but revised paragraph (c)(3) so that the paragraph (b)(2) requirements only apply when the SSC as a body or individual SSC members participate in a peer review process established under MSA section 302(g)(1)(E). The revision allows for less formal SSC review of information that is not novel, controversial or influential, such as a routine update of a stock assessment. Peer reviewers, including SSC members, participating in a peer review process established pursuant to MSA section 302(g)(1)(E) must meet the applicable OMB peer review standards as adopted in the revised NS2 guidelines. The revised NS2 guidelines are consistent with MSA section 302(g)(1)(D) which specifies that each SSC member shall be treated as an affected individual for the purposes of paragraphs (2), (3)(B), (4), and (5)(A) of MSA section 302(j). Further details on the conflicts of interest disclosure of SSC members as affected individuals are provided at 50 CFR 600.235. Regarding the comment that the SSC is the final arbiter in the peer review process, we agree that the SSC review is the final step in the overall scientific review process and the SSC should certify that its scientific recommendations for its Council are based on the BSIA. The revised NS2 guidelines do not restrict or impinge on the SSC's responsibilities to its Council.

Comment 53: Some commenters suggested that the SSC's role is advisory and should not invade the province of the Council decision making ability. They stated that the Council shall take into consideration the recommendations of the SSC, any public comment, and peer review findings in decision making.

Response: We agree that the role of the SSC is advisory and the revised NS2 guidelines in no way preclude any Council's consideration of public comments or other information when making decisions. However, the NS2 guidelines encourage all scientific information considered by the Council, including peer reviews, be brought to the Council through its SSC. We also note that pursuant to section 302(h)(6) of the MSA, a Council may not exceed fishing level recommendations of its SSC when establishing ACLs. See the NS1 guidelines (50 CFR 600.310) for further explanation.

Comment 54: Commenters suggested paragraph (b)(2)(iii) could be misinterpreted to indicate that federal and state fishery agency scientists could not serve as SSC members to review data or scientific materials prepared by their respective agencies. One commenter suggested amending the guidelines to prevent SSC members who are state or NMFS employees with unique scientific qualifications from being disqualified on conflict of interest grounds. A commenter also asked for clarification on whether SSC members, including state or territorial officials, who advance an agenda at odds with Council decisions, should be screened for conflicts of interest.

Response: The guidelines provide that peer reviewers, including the SSC or SSC members who participate in peer review, must satisfy the peer review standards, and federal employees conducting peer review must comply with all applicable federal ethics requirements. The NS2 guidelines are clear regarding SSC participation in peer review and do not impose a blanket prohibition on employees from state or federal agencies, including NMFS, from participating in peer review. For clarity, we agree to remove, ''reviewers should not be employed by the Council or entity that produced or utilizes the product for management decisions'' in paragraph (b)(2)(iii). This also resolves the ambiguity of the word ''entity,'' which was too vague. Additional details on the conflict of interest disclosure requirements for SSC members are provided at 50 CFR 600.235.

Comment 55: One commenter requested clarification of paragraph (c) by inserting ''evaluation'' in the title and first sentence to read: ''Scientific evaluation and advice to Council'' and: ''Each scientific and statistical committee shall provide its Council ongoing scientific evaluation and advice for fishery management decisions.''

Response: Paragraph (c) quotes MSA section 302(g)(1)(B) verbatim, therefore NMFS did not revise that language in the final guidelines. Moreover, NMFS believes that the SSC's role in evaluating scientific information is adequately addressed in paragraph (c)(1) which states: ''Debate and evaluation of scientific information is the role of the SSC.''

Comment 56: One commenter requested that the NS2 guidelines include guidance on the SSC process itself, because there is no oversight of the SSC and the SSC process is neither free of bias and conflict, nor amenable to alternative points of view. Other commenters requested the addition of language to address a perception of philosophical bias or advocacy by some SSC members.

Response: NMFS believes that the revised guidelines provide clear guidance on the peer review standards and the SSC's role as scientific advisors to its Council. Pursuant to MSA section 302(f)(6), Councils are required to make available to the public a Statement of Organization, Practices and Procedures (SOPP) in accordance with uniform standards prescribed by the Secretary of

Commerce. (See 16 U.S.C. 1852(f)(6).) The purpose of the SOPP is to inform the public how the Council (including the SSC and advisory panels) operates. (See 50 CFR 600.115.) The Council SOPP provides the best practices and operating procedures for the Council's SSC. Regarding alleged bias and conflict in the SSC process, MSA section 302(g)(1)(D) requires disclosure of SSC members' financial interests, and details on SSC member conflict of interest disclosure are provided at 50 CFR 600.235. Regarding openness of SSCs to alternative points of view, the SSC is comprised of experts from academic, non-governmental, and Federal and state government entities who provide expertise over a range of disciplines needed for informed fishery management decisions.

Comment 57: One commenter requested striking the statement: ''the SSC must have a peer review of all of its recommendations'' in the proposed guidelines.

Response: This statement does not exist in the proposed guidelines, nor do the guidelines require the SSC recommendations to be peer reviewed. Paragraph (c)(1) states that: ''SSC scientific advice and recommendations to its Council are based on scientific information that the SSC determines to meet the guidelines for best scientific information available as described in paragraph (a) of this section.''

Comment 58: One commenter suggested replacing ''information'' with ''data'' in the paragraph (c)(1) statement: ''Such scientific advice should attempt to resolve conflicting scientific information, so that the Council will not need to engage in debate on technical merits.''

Response: NMFS did not make the suggested change because the scientific information considered by the SSC is not always strictly data. For example, the SSC often evaluates scientific data, methods, results, and conclusions.

Comment 59: NMFS received several comments on the importance of transparency of the SSC when providing evaluation and advice to its Council; however, some expressed concern that meetings of the SSC were not publicly transparent. One commenter suggested that the NS2 guidelines should bar SSC meetings that are not public, including closed conference call meetings, and stated that some SSCs do not even meet concurrently with Council meetings, thereby preventing input from constituents. Another commenter suggested adding ''must'' to paragraph (c)(3) to read: ''When the SSC as a body is conducting peer review, it should strive for consensus and must meet the transparency guidelines for best scientific information available and peer reviews as described in paragraphs (a)(6)(iv) and (b)(3) of this section,'' because it is essential that the SSC, in the capacity of a peer reviewer, be transparent.

Response: The NS2 guidelines clearly state that review of scientific information by the SSC should be transparent and paragraph (c)(3) has been revised as requested. MSA section 302(i)(2) mandates that SSC meetings be open to the public and that timely notice be published in the **Federal Register**. SSC evaluations, findings, and recommendations are documented for Council meetings, which are also open to the public.

Comment 60: One commenter indicated that the SSC (or other Council advisory bodies), when conducting peer review, does not have to meet the high standards of the OMB peer review criteria. It was suggested that, in some instances, decisions on the use of updated stock assessment information have been made by the Councils and their SSCs without prior review by the established stock assessment review processes.

Response: NMFS agrees that the majority of work conducted by the SSC and other advisory bodies are not peer review processes, but rather advisory responsibilities, and the Council's SOPP provides guidance on best practices and operating procedures for the Council's SSC and other advisory bodies. Details on SSC member conflict of interest disclosure are provided at 50 CFR 600.235. Peer reviewers, including SSC members that participate in peer review, are required to satisfy the OMB peer review standards, where applicable. The NS2 guidelines also specify: ''For peer review of some work products or scientific information, a greater degree of independence may be necessary to assure credibility of the peer review process.'' For example, an assessment update may not require the same degree of independence in the peer review process as would a benchmark assessment. NMFS notes that all stock assessment information undergoes some degree of peer review prior to the SSC evaluation for its Council.

Comment 61: A commenter recommended including a requirement for Council approval before any SSC member could be selected for an outside peer review, to mitigate the potential for any real or perceived conflicts of interest for SSC recommendations to its Council.

Response: We do not believe that the recommended revision is necessary. The NS2 guidelines clearly state: ''Participation of an SSC member in a peer review should not impair the ability of that SSC member to accomplish the advisory responsibilities to the Council.''

Comment 62: One commenter suggested revising subsection (c)(2) to reflect that, to the extent possible, service on peer review panels should rotate between qualifying SSC members to strive for independence, balance and an absence of potential bias on review panels.

Response: NMFS believes that this recommendation is already adequately addressed in paragraph (b)(2)(iii) of the guidelines, which recommends rotating peer review responsibilities across an available pool of qualified reviewers.

Comment 63: Paragraph (b)(2) states: ''The selection of participants in peer review must be based on expertise, independence, and a balance of viewpoints . . .'' One commenter recommended removing the implication that the SSC is not itself ''balanced'' with respect to scientific perspectives. The commenter noted that the SSC includes scientists employed by the states, the Federal government, international commissions, and universities, and questioned whether the SSC members, for example government members, are to be considered as having some ''perspective'' that needs to be balanced with other perspectives and, therefore, whether additional SSC members must be appointed.

Response: NMFS believes that this is a misinterpretation of the guidelines because the guidelines do not provide any requirements on the selection of SSC as an advisory body to its Council and do not imply that the SSC body is not itself balanced. Paragraph (b)(2) adopts the criteria from the OMB Peer Review Bulletin requiring that the selection of peer reviewers, including SSC members that participate in peer review, be based on expertise, independence, balance of viewpoints, and be free of conflicts of interest.

Comment 64: Commenters requested removing the phrase ''conducts or'' from the statement in paragraph (c)(3): ''If an SSC as a body, or individual members of an SSC, conducts or participates in a peer review, those SSC members must meet the peer reviewer selection criteria.''

Response: NMFS revised the statement to read: ''If an SSC as a body conducts a peer review established under [MSA] section 302(g)(1)(E) or individual members of an SSC participate in such a peer review, the SSC members must meet the peer reviewer selection criteria as described

in paragraph (b)(2) of this section.'' See the response to Comment 52 for additional detail.

Comment 65: One commenter recommended that NMFS and the Councils establish terms of reference requiring SSC members to serve as chairs or facilitators in peer review, a role in which they may serve without having to meet strict qualifying criteria for peer reviewers.

Response: NMFS agrees that it may be beneficial to the Council to have an SSC member serve as a chair during a peer review. The revised NS2 guidelines allow for this and NMFS does not believe additional language is necessary because the Secretary and each Council have the discretion to establish the peer review process, including who should serve as the chair of the review. Paragraph (c)(2) clearly states: ''An SSC member may participate in peer review when such participation is beneficial to the peer review due to the expertise and institutional memory of that member, or beneficial to the Council's advisory body by allowing that member to make a more informed evaluation of the scientific information.''

Comment 66: One commenter requested that paragraph (c)(3) clearly distinguish regular peer review activities of the SSC from official peer reviews which require SSC members participating in the review to meet the peer reviewer standards in paragraph (b)(2).

Response: NMFS agrees and clarified in paragraph (c)(3) that SSC members must meet the peer reviewer selection criteria contained in paragraph (b)(2) when they participate in a peer review established pursuant to MSA section 302(g)(1)(E). See the responses to Comments 52 and 60 for additional detail.

Comment 67: Several commenters expressed support for paragraph (c)(5), which requires that SSC disagreements with peer review findings be documented in a report and made available to their Council and the public. Some commenters requested stronger language to prevent the SSC from freely rejecting the results of any peer review. Other commenters suggested that the scientific advice of the SSC should attempt to resolve conflicting scientific information, and the analysis of conflicts should be reported so that the Council will not be forced to engage in debate on technical merits. The SSC should reconcile the differences between its findings and that of the peer review. One commenter requested an additional 45–60 day period for public review of the peer review report and SSC findings when an SSC reports disagreements with the findings and conclusions of a peer review. Another commenter supports the idea that the SSC should report its decisions that are inconsistent with a peer review finding, but expressed concern that paragraph (c)(5) implies that a peer review panel is an independent policy and review body with standing equal to that of the SSC or Council.

Response: Paragraph (c)(1) provides appropriate guidance that the SSC's scientific advice should attempt to resolve conflicting scientific information. Further, paragraph (c)(5) provides that when the SSC disagrees with peer review results, a report must be prepared outlining the areas of disagreement, and the rationale and information used by the SSC for making its determination. Paragraph (c)(5) does not state or imply that a peer review panel has equal standing to that of the SSC and Council; rather, the intent is to ensure transparency in the SSC evaluation of scientific information that is inconsistent with the findings or conclusions of a peer review. NMFS disagrees with the request to require an additional 45–60 day period for public review when the SSC reports disagreements with the findings and conclusions of a peer review because it would significantly delay final Council action on fishery management measures.

Comment 68: One commenter requested that the NS2 guidelines require any additional assessment work requested by the SSC be subject to peer review. The commenter explained that SSCs in some regions have extended stock assessments by requiring additional model runs, which are then incorporated into scientific advice to the Council without further peer review.

Response: NMFS does not agree that the NS2 guidelines should in all cases require peer review of additional work requested by the SSC. When the SSC requests additional work, it should be for the purpose of clarification in the context of a main body of work that has already been reviewed. The need for peer review of additional work will depend upon the novelty, complexity, and potential for controversy. The peer review system can involve existing committees, so it may be acceptable for the SSC to act as reviewers for the added work if any review is needed. It is important that this additional work be documented in the SAFE report or elsewhere so that it becomes part of the public record for fishery management actions.

Comment 69: One commenter expressed concern with language in paragraph (c)(4) that states that the SSC should, ''not repeat the previously conducted and detailed technical peer review,'' on the basis this implies that SSC input is not warranted if a peer review is conducted. The commenter recommended adding, ''but this provision is not intended to thwart or constrain the scope or depth of SSC comments.''

Response: Paragraph (c)(4) is not intended to constrain the advisory role of the SSC to its Council, but seeks to ensure that a technical peer review is not repeated. A primary role and necessary function of the SSC is to evaluate and provide recommendations on scientific information for its Council, including recommendations on whether the scientific information is adequate or requires further work if deemed inadequate.

Comment 70: Some commenters requested clarification of the roles of the SSC and Council regarding establishment of ABCs and ACLs. One commenter stated that the NS2 guidelines should include a definitive statement that SSCs provide science-based ABCs and Councils set ACLs. Some commenters requested revising the language in paragraph (c)(6) to: ''Annual catch limits (ACLs) may exceed the SSC's recommendations for fishing levels.'' Other commenters stated that, once the SSC has set the ABC, the options of the Councils are extremely limited. The NS2 guidelines should clarify that the Councils must have the power and ability to determine the proper limits and regulations based on the recommendations of the SSCs.

Response: The NS1 guidelines provide detailed guidance on compliance with the ACL requirements and clarify the relationship between ACLs, ABC, maximum sustainable yield (MSY), optimum yield (OY) and other applicable reference points. (See generally 50 CFR 600.310.) Those issues are not addressed in the NS2 guidelines. NMFS will not make the suggested revisions to the language in paragraph (c)(6) because doing so would be inconsistent with MSA section 302(h)(6) which states that: ''Each Council shall . . . develop annual catch limits for each of its managed fisheries that may not exceed the fishing level recommendations of its scientific and statistical committee or the peer review process established under subsection (g).''

SAFE Report

Comment 71: One commenter requested that the guidelines specify that the SAFE report be a single document, or alternatively provide that the SAFE documents be available in one

place on a Council or NMFS Web site with an index and links to pertinent documents. Most commenters agreed with the SAFE report being a ''document or set of documents'' and with the new language in paragraph (d)(5)(ii) that the SAFE report: ''must be made available by the Council or NMFS on a readily accessible Web site.'' Two commenters recommended retaining the current NS2 guidelines language: ''Each SAFE report must be scientifically based, and cite data sources and interpretations'' and recommended that the Secretary ensure disclosure of the source of any information included in the SAFE report.

Response: While NMFS understands that a single document has certain advantages of convenience to the users, NMFS decided that it is more beneficial to provide the Councils and the Secretary the discretion to choose whether to compile the SAFE report as a single document or set of documents. In response to comments on the proposed guidelines, NMFS has added language in paragraph (d) stating that: ''Each SAFE report must be scientifically based, with appropriate citations of data sources and information.'' NMFS adds further clarification in paragraph (d)(5)(i): ''Sources of information in the SAFE report should be referenced unless the information is proprietary.''

Comment 72: One commenter requested adding ''and the Secretary'' to the first sentence of paragraph (d) to indicate that the SAFE report is for both the Secretary and Council. Some commenters suggested that the NS2 guidelines should explicitly delegate to NMFS or the Councils the accountability for preparing the SAFE report with support from others as needed.

Response: Paragraph (d) was revised to state that the SAFE report: ''provides the Secretary and Councils with a summary of scientific information . . .'' The NS2 guidelines explicitly designate responsibility in paragraph (d)(1): ''The Secretary has the responsibility to ensure that SAFE reports are prepared and updated or supplemented as necessary . . .'' while also providing that: ''The Secretary or Councils may utilize any combination of personnel from Council, State, Federal, university, or other sources to acquire and analyze data and product the SAFE report.'' The intent is to allow flexibility between the Secretary and Councils in utilizing their resources to compile the SAFE report.

Comment 73: One commenter objected to the language in paragraph (d) because it appears to give NMFS the responsibility to prepare the SAFE report, making NMFS the final arbiter of what constitutes BSIA for the Councils. It also appears to require that the SAFE report be peer reviewed before it can be considered by a Council, which usurps the SSC's role of providing scientific advice to the Council. Another commenter requested that each SAFE report, particularly new information, be peer reviewed and that all sources used to compile the SAFE reports should be free of conflicts of interest.

Response: As reflected in paragraph (d), the Secretary of Commerce ultimately has the responsibility under the MSA to determine whether a proposed management action is based on BSIA, because all fishery management actions must be determined to be consistent with all of the MSA national standards, including NS2, as well as other applicable law. While it is expected that the advice provided by SSCs will be based on BSIA, that information, as well as how it is applied, is still subject to Secretarial review and approval before it can be implemented. There is no language in paragraph (d) that implies that the Secretary's responsibility in regard to the SAFE report undermines the role of the SSC. Peer review of scientific information, including information contained in SAFE reports, and conflict of interest concerns are sufficiently addressed in the peer review section of these revised guidelines. The guidelines are clear that the SAFE report is a compilation of the BSIA products, some of which may have been peer reviewed, to be used by the Secretary, Councils, and the public in developing and reviewing fishery management actions. The SAFE report is an important and useful summary of scientific information for evaluation and recommendations by the SSC for its Council.

Comment 74: One commenter recommended that the NS2 guidelines specify a standard format for SAFE reports, similar to a format of the North Pacific groundfish SAFE reports where individual stock assessments are summarized in an executive summary including relevant information, such as biological reference points and stock status, as well as recommendations for OFLs and ABCs, and the concerns addressed in these recommendations.

Response: NMFS considered requiring a common format for SAFE reports, but recognized that there are significant differences in how the eight Councils and the Secretary conduct their business, including their management schedules, the committees and technical groups involved, how and when they receive scientific information, and the format in which that information is received. In consideration of those differences and the need to make the SAFE report preparation efficient, NMFS believes that allowing flexibility in the format of the SAFE documents is preferable to requiring a single uniform format.

Comment 75: One commenter requested that the SAFE report include information on safety at sea, as specified in the National Standard 10 guidelines.

Response: Paragraph (d)(2) of the revised NS2 guidelines states that SAFE reports provide ''information on bycatch and safety for each fishery.''

Comment 76: Commenters indicated that some regions have not routinely prepared SAFE reports, and requested the SAFE report be updated regularly, on at least an annual basis to ensure consistency with any and all management decisions.

Response: NMFS believes paragraph (d)(1) is sufficiently clear that: ''The SAFE report and any comments or reports from the SSC must be available to the Secretary and Council for making management decisions for each FMP'' and also states: ''The Secretary has the responsibility to ensure that SAFE reports are prepared and updated or supplemented as necessary whenever new information is available to inform management decisions. . .'' NMFS disagrees with the recommendation that the SAFE report be updated on at least an annual basis because, in some cases, Council processes may allow for multiyear harvest specifications. NMFS believes allowing the SAFE reports to be prepared periodically is appropriate and consistent with the decision-making schedule to allow for efficiencies and differences in the processes used by different Councils for different fisheries.

Comment 77: One commenter recommended that the text in paragraph (d)(2), ''. . . assessing the relative success of existing state and Federal fishery management programs'' be revised to ''. . . assessing the relative success of existing relevant state and Federal fishery management plans.''

Response: NMFS agrees to insert the word ''relevant.'' The word ''programs'' was not changed to ''plans'' as recommended because not all states have FMPs.

Comment 78: One commenter requested inserting in paragraph (d)(3): ''To the extent possible . . .'' at the start of ''each SAFE report should contain the following'' because items to be included in a SAFE report cannot always be calculated for all stocks (*e.g.,* minimum stock size threshold cannot be calculated for data-poor stocks with incomplete catch records).

Response: NMFS agrees with the commenter's concern and revised paragraph (d)(3) as: ''Each SAFE report should contain the following scientific information when it exists.'' NMFS also added to paragraph (d)(2): ''The SAFE report should contain an explanation of information gaps and highlight needs for future scientific work.''

Comment 79: One commenter requested that the NS2 guidelines require that uncertainty be specified in the SAFE report because the ABC will be set based, in part, on scientific uncertainty. The commenter also requested the guidelines require that the SAFE report include management uncertainty information and relevant recommendations for the Council's consideration in establishing ACLs.

Response: NMFS agrees with the suggestion to include consideration of scientific uncertainty in the SAFE report, and revises the language in paragraph (d)(3)(i)(B) to read ''(B) Information on OFL and ABC, preventing overfishing, and achieving rebuilding targets. Documentation of the data collection, estimation methods, and consideration of uncertainty in formulating catch specification recommendations should be included (§ 600.310(f)(2)).'' The SSC takes into account scientific uncertainty in setting ABC control rules, and the SSC report to the Council should document how the SSC did so.

Comment 80: One commenter requested that the NS2 guidelines require the SAFE report to include definitions for ''overfishing'' and ''overfished'' from the NMFS 1998 National Standard 1 Guidelines. Another commenter stated that SAFE reports should include the SSC recommendations for ABC, and must contain the maximum fishing mortality threshold (MFMT), the minimum stock size threshold (MSST), overfishing and overfished status, and rebuilding plans if applicable. Another commenter suggested that the SAFE report contain assessment team recommendations for OFLs and ABCs, including any concerns that went into their recommendations and this information should then be evaluated by the SSC for their Council's catch specification process. Another commenter expressed concern with the requirement that the SAFE report include recommendations and reports of the SSC regarding overfishing levels and ABCs because the SAFE report is published before the SSC evaluation. The SAFE report is reviewed by the SSC as it provides its advice to the Council, and its recommendations occur after the publication of the SAFE report. Therefore, the SSC should publish a report of its deliberations and make it publicly available on the Council's Web site as part of the official record supporting the Council's recommendations to the Secretary.

Response: NMFS disagrees with the suggestion to require definitions for ''overfishing'' and ''overfished'' in the SAFE report because those terms are already defined in the NS1 guidelines. We believe the information on which to base catch specifications and status determinations should be available to the Councils at the time of their decision making process, and therefore, language is added to paragraph (d)(3)(i) that the SAFE report should contain: ''Information on which to base catch specifications and status determinations, including the most recent stock assessment documents and associated peer review reports, and recommendations and reports from the Council's SSC.'' Regarding the comment on the requirement that the SAFE report include SSC reports on overfishing levels and ABCs, NMFS believes this concern is adequately addressed in the NS2 guidelines because the SAFE report can be a document or set of documents, including the report of the SSC findings and recommendations, that are publicly available. The final recommendations and actions of the SSC may be included in an amendment to the SAFE report.

Comment 81: Two commenters expressed concern with the text in paragraph (d)(3): ''Each SAFE report should contain . . . (i)(B) Any management measures necessary to rebuild an overfished stock or stock complex . . .'' The SAFE report should report progress towards stock rebuilding, but rebuilding plans, including analysis of management alternatives, should be developed through the Council's FMP process with input from advisors and the public.

Response: The revised NS2 guidelines specify that the SAFE report should contain the scientific information needed in support of management measures or rebuilding plan, and the intent was not to include the actual management measures or the full analyses of the alternatives. MSA section 303 requires FMPs and FMP amendments to contain conservation and management measures for fisheries. To clarify this, NMFS has deleted ''along with information to determine'' from paragraph (d)(3)(i)(A), so it now reads: ''A description of the SDC (*e.g.,* maximum fishing mortality rate threshold and minimum stock size threshold for each stock or stock complex in the fishery).'' NMFS also revised paragraph (d)(3)(i)(B) to read: ''The best scientific information available to determine whether overfishing is occurring with respect to any stock or stock complex, whether any stock or stock complex is overfished. . .'' Paragraph (d)(3)(i)(C) was revised to read: ''The best scientific information available in support of management measures necessary to rebuild an overfished stock or stock complex (if any) in the fishery to a level consistent with producing the MSY in that fishery.'' These changes make clear that the purpose of the SAFE report is to provide the Councils and Secretary with the necessary BSIA to understand the status of the fishery and support their efforts in evaluating management measures and alternatives.

Comment 82: One commenter urged that paragraph (d)(3)(iii) incorporate the Standardized Bycatch Reporting Methodology (SBRM) required by MSA section 303(a)(11), 16 U.S.C. 1853(a)(11), into the SAFE report. The SAFE report also should include information on catch and bycatch, a description of pertinent data collection and estimation methods, and ''quantitative estimates'' of total mortality.

Response: Paragraph (d)(3)(ii) of the revised NS2 guidelines states that the SAFE report should include: ''Information on sources of fishing mortality (both landed and discarded), including commercial and recreational catch and bycatch in other fisheries and a description of data collection and estimation methods used to quantify total catch mortality, as required by the National Standard 1 Guidelines.'' The NS2 guidelines do not preclude including discard and total mortality estimates into the SAFE report when available. NMFS believes it is inappropriate to require SAFE reports to contain SBRM, as MSA section 303(a)(11) requires that SBRM be established in an FMP.

Comment 83: Two commenters expressed concern that paragraph (d)(3)(v) could be misinterpreted as requiring the relevant evaluations of EFH information to be in the SAFE report. EFH information should be evaluated through Plan Teams, SSC and Council meetings. The frequency of review and revision of EFH components of FMPs is already provided for in 50 CFR 600.815(a)(10), therefore it would be confusing to require additional EFH review as part of the SAFE report. Another commenter indicated that this confusion can be resolved with minor clarification that EFH information may be included by reference and contained in a stand-alone separate document, not just physically merged into the SAFE report.

Response: The NS2 guidelines ensure that a summary of BSIA is available in the SAFE report, including any relevant EFH information. The intent is not to require an additional evaluation of EFH. Therefore, NMFS has deleted ''review and evaluations'' and ''stand-alone chapter'' from paragraph (d)(3)(iv) so it now reads: ''Information on EFH to be included in accordance with the EFH provisions (§ 600.815(a)(10)).''

Comment 84: One commenter requested language requiring more thorough assessments of marine ecosystems in SAFE reports. Two commenters supported the inclusion of: ''Pertinent economic, social, community, and ecological information'' in paragraph (d)(3)(vi) and one suggested additional language that explicitly includes ecosystem considerations, such as forage fish impacts and other criteria to determine optimum yield.

Response: NMFS believes that the NS2 guidelines include sufficient language on the scientific information to be included in the SAFE report, including marine ecosystem information. The SAFE report is a summary of existing information, not only on stock status, but on many ecosystem components as well. The language is intended to be broad enough to include all the important considerations in ecological information, including forage fish impacts where relevant.

FMPs

Comment 85: One commenter requested insertion of the language: ''BSIA is needed for regulatory amendments in conjunction with a framework FMP, and not just FMPs.''

Response: The proposed edit is not necessary because the MSA national standards apply to all Council actions, not just FMPs.

Comment 86: One commenter requested adding: ''If information indicates that drastic changes have occurred in the fishery that require revision of the management objectives or measures, then the FMP process must begin again.''

Response: This is beyond the scope of the guidelines and is unnecessary. Councils have the statutory responsibility for preparing FMPs and amendments to such plans and revising them as appropriate according to sections 302(h) and other provisions of the MSA.

Comment 87: One commenter asserted that the preparation and implementation of an FMP should be delayed until the best scientific data possible concerning a fishery is complete.

Response: NMFS disagrees and provides in paragraph (e)(2): ''The fact that scientific information concerning a fishery is incomplete does not prevent the preparation and implementation of an FMP.'' This is consistent with the NS2 requirement that fishery conservation and management measures be based on the BSIA.

Comment 88: One commenter stated the NS2 guidelines should apply equally to Highly Migratory Species (HMS) managed by NMFS and Council-managed species. The commenter also requested that the guidelines address how scientific advice for HMS is provided to NMFS.

Response: The NS2 guidelines apply to scientific information used by the Councils and NMFS. Scientific information used by NMFS to manage Atlantic HMS undergoes a rigorous and transparent peer review process. No additional HMS-specific provisions are needed in the guidelines.

Comment 89: One commenter suggested that clarification is needed in paragraph (e)(3): ''Information about harvest within state waters, as well as in the EEZ, may be collected if it is needed for proper implementation of the FMP and cannot be obtained otherwise.'' The commenter recommended that the NS2 guidelines specify FMP information requirements that may be imposed on fisherman and processors.

Response: Information to be collected from fishermen and processors must be identified in FMPs per MSA section 303(a)(5). Thus NMFS has not revised the NS2 guidelines to require specification of this information. However, NMFS has added a new sentence in paragraph (e)(3) that clarifies: ''Scientific information collections for stocks managed cooperatively by Federal and State governments should be coordinated with the appropriate state jurisdictions, to the extent practicable, to ensure harvest information is available for the management of stocks that utilize habitats in state and federal managed waters.''

Comment 90: Four commenters requested that the words ''should'' or ''must'' be replaced with the word ''shall'' through many sections to strengthen the requirements of NS2. Conversely, two commenters noted that MSA section 301(b) provides that the National Standards guidelines are advisory in nature and do not have the force and effect of law, and therefore recommended that NMFS strike all use of the words ''must'' and ''shall'' in the NS2 guidelines.

Response: In the NS2 guidelines, ''shall'' is used only when quoting statutory language directly. ''Must'' is used instead of ''shall'' to denote an obligation to act and is primarily used when referring to requirements of the MSA, the logical extension thereof, or other applicable law. ''Should'' is used to indicate that an action or consideration is strongly recommended to fulfill the Secretary's interpretation of the MSA, and is a factor reviewers will look for in evaluating a SOPP or FMP. ''May'' is used in a permissive sense. NMFS notes that the above word usage in the National Standards guidelines is explained at 50 CFR 600.305(c).

V. Changes From Proposed Action (74 FR 65724, Dec. 11, 2009)

Paragraph (a)(1) was revised to clarify that ''environmental'' scientific information is also important for fishery conservation and management. This introductory paragraph was revised to clarify that successful fishery management not only depends on evaluation of ''potential'' impact that conservation and management measures will have on living marine resources, but also depends on ''(ii) Identifying areas where additional management measures are needed.''

Paragraph (a)(2) was revised by striking the last sentence because similar language is provided in paragraph (a)(6)(v).

Paragraph (a)(3) was revised to expand the term ''data-poor fisheries'' to ''Information-limited fisheries, commonly referred to as 'data-poor' fisheries.''

Paragraph (a)(4) was revised by adding: ''Scientific information includes established and emergent scientific information. Established science is scientific knowledge derived and verified through a standard scientific process that tends to be agreed upon often without controversy. Emergent science is relatively new knowledge that is still evolving and being verified, therefore, may potentially be uncertain and controversial. Emergent science should be considered more thoroughly, and scientists should be attentive to effective communication of emerging science.'' Editorial clarification was also included in the revised language: ''Scientific information includes data compiled directly from surveys or sampling programs, and models that are mathematical representations of reality constructed with primary data.''

Paragraph (a)(5) provides a description of science as a dynamic process, and the word ''ideally'' was added to the statement that: ''Best scientific information is, therefore, not

static and ideally entails developing and following a research plan with the following elements'' because the ability to achieve all the listed elements is not always possible.

Paragraph (a)(6) was revised to replace ''Principles'' with ''Criteria to consider'' to read as: ''Criteria to consider when evaluating best scientific information are . . .''

Paragraph (a)(6)(i) was revised to clarify that analysis of related stocks or species for inferring the likely traits of stocks ''may be a useful tool'' rather than the previously stated ''is a powerful tool.''

Paragraph (a)(6)(ii)(B) was revised to clarify ''Alternative points of view'' as ''Alternative scientific points of view.''

Paragraph (a)(6)(ii)(C) was revised to remove ''reconcile'' and the ambiguity associated with the previous statement: ''effort should be made to reconcile scientific information with local and traditional knowledge.'' The language now reads: ''Relevant local and traditional knowledge (e.g., fishermen's empirical knowledge about the behavior and distribution of fish stocks) should be obtained, where appropriate, and considered when evaluating the BSIA.''

Paragraph (a)(6)(iii) was revised by striking the first sentence of the paragraph and revising the second sentence from: ''The objectivity standards should ensure that information is accurate, reliable, and unbiased, and that information products are presented in an accurate, clear, complete, and balanced manner'' to read: ''Scientific information should be accurate, with a known degree of precision, without addressable bias, and presented in an accurate, clear, complete and balanced manner.'' We also included the statement: ''Scientific processes should be free of undue nonscientific influences and considerations'' as recommended by the NRC (2004).

In paragraph (a)(6)(iv), the statement: ''Subject to the Magnuson-Stevens Act confidentiality requirements, the public should have access to each stage in the development of scientific information, from data collection, to analytical modeling, to decision making'' was removed because it is impracticable to solicit public comment during all the stages of development of the science, such as data sampling operations and analytical work. Further revision was made to clarify public comment should be solicited during the ''review'' of scientific information rather than during the ''development'' of science.

Paragraph (a)(6)(v) on timeliness was revised by moving paragraph (a)(6)(v)(B) to the beginning of paragraph (a)(6)(v), and then relabeling paragraph (C) as (B). The last sentence from (B) was moved to be the first sentence in (a)(6)(v), and this phrase: ''Management decisions should not be delayed due to data limitations . . .'' was revised to: ''Mandatory management actions should not be delayed due to limitations in scientific information . . .''

In paragraph (a)(6)(v), the statement: ''Sufficient time should be allotted to analyze recently acquired data to ensure its reliability and that it has been audited'' was modified for clarification to: ''Sufficient time should be allotted to audit and analyze recently acquired information to ensure its reliability.'' Further clarification is provided by revising: ''Data collection methods are expected to be subjected to appropriate review before used to inform management decisions'' to: ''Data collection methods are expected to be subjected to appropriate review before providing data used to inform management decisions.'' The text of proposed paragraph (a)(6)(v)(B) was revised by changing: ''Timeliness may also mean that in some cases results of important studies or monitoring programs must be brought forward'' to: ''In some cases, due to time constraints, results of important studies or monitoring programs may be considered for use before they are fully completed.''

Paragraph (a)(6)(v)(A) was revised by changing: ''For those data that require being updated'' to: ''For information that needs to be updated. . .'' The words ''In particular,'' were removed. The words ''such timing concerns'' were added to language that now reads: ''subject to regulatory constraints, and such timing concerns should be explicitly considered. . .'' Further clarification was added with: ''Data collection is a continuous process, therefore analysis of scientific information should specify a clear time point beyond which new information would not be considered in that analysis and would be reserved for use in subsequent analytical updates.''

Paragraph (a)(6)(v)(C) was merged with paragraph (B), and revised for clarity by changing ''species' life history characteristics might not change'' to ''some species' life history characteristics might not change.'' Another revision changed: ''Other time-series data (e.g., abundance, catch statistics, market and trade trends) provide context for changes in fish populations, fishery participation, and effort used, and therefore provide valuable information to inform current management decisions'' to read: ''Other historical data (e.g., abundance, environmental, catch statistics, market and trade trends) provide time-series information on changes in fish populations, fishery participation, and fishing effort that may inform current management decisions.''

Paragraph (a)(6)(vi)(B) was revised to clarify the list of validation measures by changing: ''the precision of the estimates is adequate, model estimates are unbiased, and the estimates are robust to model assumptions'' to: ''the accuracy and precision of the estimates is adequate, and the estimates are robust to model assumptions.'' The phrase ''and to correct for known bias to achieve accuracy'' was added to the statement: ''models should be tested using simulated data from a population with known properties to evaluate how well the models estimate those characteristics.''

In paragraph (a)(6)(vii) a new sentence was added for additional clarity: ''Routine updates based on previously reviewed methods require less review than novel methods or data.'' We also provided clarification by revising: ''substantial fishery management alternatives considered by a Council'' to: ''The scientific information that supports conservation and management measures considered by the Secretary or a Council should be peer reviewed, as appropriate.''

Paragraphs (a)(6)(vii) and (viii) were combined into a single paragraph. A new sentence was added to the end of the paragraph: ''Other applicable guidance on peer review can be found in the Office of Management and Budget Final Information Quality Bulletin for Peer Review.''

Paragraph (b)(1) was revised by removing ''for each Council'' from the phrase: ''The process established by the Secretary and Council for each Council . . .''

The first sentence of paragraph (b)(1)(ii) was revised by moving ''to the extent practicable'' from the end of the sentence to read: ''The peer review should, to the extent practicable, be conducted early . . .'' and adding: ''so peer review reports are available for the SSC to consider in its evaluation of scientific information for its Council and the Secretary'' to the end of the sentence.

Paragraph (b)(1)(iii) was revised by changing: ''The scope of work contains the objective of the specific advice being sought'' to: ''The scope of work contains the objectives of the peer review, evaluation of the various stages of the science, and specific recommendations for improvement of the science.'' The language: ''as well as to make recommendations regarding areas of missing information, future research,

data collection, and improvements in methodologies'' was added to the third sentence of the paragraph. Further clarification was made by revising: ''The scope of work may not request reviewers to provide advice on scientific policy (e.g., amount of uncertainty that is acceptable or amount of precaution used in an analysis)'' to: ''The scope of work may not request reviewers to provide advice on policy or regulatory issues (e.g., amount of precaution used in decision-making) which are within the purview of the Secretary and the Councils, or to make formal fishing level recommendations which are within the purview of the SSC.''

Paragraph (b)(2) on peer review selection was revised by changing a ''must'' to a ''should.''

Paragraph (b)(2)(i) was revised by deleting ''including a balance in perspectives'' from the first sentence and adding ''should reflect a balance in perspectives, to the extent possible'' to the second sentence.

Paragraph (b)(2)(ii) was revised by deleting the second sentence and replacing it with the last sentence of this section which was revised to: ''Potential reviewers who are not federal employees must be screened for conflicts of interest in accordance with the NOAA Policy on Conflicts of Interest for Peer Review Subject to OMB's Peer Review Bulletin or other applicable rules or guidelines. ''Under the NOAA policy'' was added to the beginning of the third sentence and: ''Peer reviewers must not have any real or perceived conflicts of interest'' was changed to: ''peer reviewers must not have any conflicts of interest . . .''

Paragraph (b)(2)(ii)(C) was merged with paragraph (b)(2)(ii)(B). The language: ''Except for those situations in which a conflict of interest is unavoidable, and the conflict is promptly and publicly disclosed'' was revised to: ''For reviews requiring highly specialized expertise, the limited availability of qualified reviewers might result in an exception when a conflict of interest is unavoidable; in this situation, the conflict must be promptly and publicly disclosed.'' The last sentence of the paragraph was modified and moved to paragraph (b)(2)(ii) as noted above.

Paragraph (b)(2)(iii) addressing independence in peer review was clarified by revising: ''Peer reviewers must not have participated in the development of the work product or scientific information under review'' to: ''Peer reviewers must not have contributed or participated in the development of the work product or scientific information under review.'' The language: ''For peer review of some work products or scientific information, a greater degree of independence may be necessary to assure credibility of the peer review process'' was revised for clarity to: ''For peer review of products of higher novelty or controversy, a greater degree of independence is necessary to ensure credibility of the peer review process.'' The language: ''Peer review responsibilities should rotate across the available pool of qualified reviewers or among the members on a standing peer review panel, recognizing that, in some cases, repeated service by the same reviewer may be needed because expertise'' was revised for clarity to: ''Peer reviewer responsibilities should rotate across the available pool of qualified reviewers or among the members on a standing peer review panel to prevent a peer reviewer from repeatedly reviewing that same scientific information, recognizing that, in some cases, repeated service by the same reviewer may be needed because of limited availability of specialized expertise.''

Paragraph (b)(3) on transparency in peer review was revised from: ''A transparent process is one that allows the public full and open access to peer review panel meetings, background documents, and reports, subject to Magnuson-Stevens Act confidentiality requirements'' to: ''A transparent process is one that ensures that background documents and reports from peer review are publicly available, subject to Magnuson-Stevens Act confidentiality requirements, and allows the public full and open access to peer review panel meetings.'' The text: ''also be publicly transparent in accordance with the Council's requirements for notifying the public meetings. The date, time, location, and terms of reference (scope and objectives)'' was replaced with: ''be conducted in accordance with meeting procedures at § 600.135.'' The time period for public notice of a peer review panel meeting was revised by changing the language to: ''Consistent with that section, public notice of peer review panel meetings should be announced in the **Federal Register** with a minimum of 14 days and with an aim of 21 days before the review. . .'' The words ''prior to review'' were removed from the statement: ''Names and organizational affiliations of reviewers also should be publicly available.''

Paragraph (c)(1) on SSC advice to its Council was revised from: ''SSC scientific advice and recommendations to the Councils based on review and evaluation of scientific information must meet the guidelines of best scientific information available'' to: ''SSC scientific advice and recommendations to its Council are based on scientific information that the SSC determines to meet the guidelines for best scientific information available.'' In the sentence: ''SSCs may conduct peer reviews, participate in peer reviews, or evaluate peer reviews to . . .'', the words ''participate in peer reviews'' were struck because participation in peer review by SSC members is addressed in the paragraph (c)(2). The language: ''. . . so that the Council will not be forced to engage in debate on technical merits. Debate and evaluation of scientific information should be part of the role of the SSC'' was changed to: ''. . . so that the Council will not need to engage in debate on technical merits. Debate and evaluation of scientific information is the role of the SSC.''

The last sentence of paragraph (c)(2) was changed from: ''Participation of an SSC member in a peer review should not impair the ability of that SSC member to accomplish the advisory responsibilities to the Council'' to: ''Participation of an SSC member in a peer review should not impair the ability of that member to fulfill his or her responsibilities to the SSC.''

The first sentence of paragraph (c)(3) was revised from: ''If an SSC as a body, or individual members of an SSC, conducts or participates in a peer review, those SSC members must meet the peer reviewer selection criteria as described in paragraph (b)(2) of this section'' to: ''If an SSC as a body conducts a peer review established under Magnuson-Stevens Act section 302(g)(1)(E) or individual members of an SSC participate in such a peer review, the SSC members must meet the peer reviewer selection criteria as described in paragraph (b)(2) of this section.'' The second sentence was changed from: ''These guidelines require separate consideration from those of § 600.235 . . .'' to: ''In addition, the financial disclosure requirements under § 600.235 . . . . apply.'' When the SSC body is conducting peer review, the word ''must'' was added to ''meet the transparency guidelines.''

In paragraph (c)(4), the statement ''SSCs must maintain their role as advisors to the Council about scientific information that comes from an external peer review process'' was changed by removing ''external'' because this statement applies to all peer review rather than only external peer review. The phrase ''be linked to'' in the first sentence was changed to ''consider'' and the word ''review'' was changed to ''consider'' in the last sentence of the paragraph for clarification.

In the first sentence of paragraph (c)(5), the phrase: ''If the evaluation of scientific information by the SSC is inconsistent with'' was changed to: ''If an SSC disagrees with'' and the word ''should'' was changed to ''must'' to strengthen the need for the SSC to prepare a report outlining disagreement with peer review findings, and NMFS added: ''This report must be made publicly available'' to the end of the paragraph.

Paragraph (c)(6) was revised by specifying that ACLs are ''developed by a Council.'' The term ''SSC recommendation'' was clarified to ''SSC fishing level recommendations.'' ''Per the National Standard 1 Guidelines,'' was added to the beginning of the second sentence. Further clarification was provided by adding: ''The SSC is expected to take scientific uncertainty into account when making its ABC recommendation (§ 600.310(f)(4)). The ABC recommendation may be based upon input and recommendations from the peer review process.''

Paragraph (d) was revised to clarify that the SAFE report provides scientific information for ''the Secretary and the Councils'' rather than to only the Councils. The language: ''Each SAFE report must be scientifically based with appropriate citations of data sources and information'' was also added to this paragraph.

Paragraph (d)(1) was revised for clarification to state that the SAFE report is prepared and updated or supplemented as necessary whenever new information is available: ''to inform management decisions such as status determination criteria (SDC), overfishing level (OFL), optimum yield, or ABC values.'' It previously read: ''that requires a revision to the status determination criteria (SDC), or is likely to affect the overfishing level (OFL), optimum yield, or ABC values.'' Clarification was also made that the SAFE report must be available to ''the Secretary and Council'' rather than to only the Council.

Paragraph (d)(2) was revised by adding: ''The SAFE report should contain an explanation of information gaps and highlight needs for future scientific work. Information on bycatch and safety for each fishery should also be summarized.'' The word ''relevant'' was also added to ''state and Federal fishery management programs'' for further clarification.

The introductory paragraph (d)(3) for the SAFE report information was revised for clarification by adding ''scientific information when it exists'' to ''Each SAFE report should contain the following.''

The subsections within paragraph (d)(3) were reordered and renumbered for clarification purposes.

The language in paragraph (d)(3)(i) was moved to paragraph (d)(3)(i)(A), and revised to clarify by removing ''along with information to determine.''

The language from paragraph (d)(3)(i)(A) was moved to paragraph (d)(3)(i)(B) and revised to clarify by adding: ''The best scientific information available to determine.''

Paragraph (d)(3)(i)(B) was renumbered as paragraph (d)(3)(i)(C) and revised to clarify by adding: ''The best scientific information in support of'' and removing the word ''any.''

In paragraph (d)(3)(ii), the language: ''Information on which to base catch specifications and status determinations, including the most recent stock assessment documents and associated peer review reports, and recommendations and reports from the Council's SSC'' was moved to paragraph (d)(3)(i) as an introductory sentence to paragraph (d). The remaining language: ''on OFL and ABC, preventing overfishing, and achieving rebuilding targets'' and: ''Documentation of the data collection, estimation methods, and consideration of uncertainty in formulating catch specification recommendations should be included'' was moved to paragraph (d)(3)(i)(B). The word ''Information'' was added before the phrase ''on OFL and ABC, preventing overfishing.''

Paragraph (d)(3)(iii) was renumbered as paragraph (d)(3)(ii).

Paragraph (d)(3)(iv) was renumbered as paragraph (d)(3)(iii).

Paragraph (d)(3)(v) was renumbered as paragraph (d)(3)(iv), and revised by changing: ''Review and evaluation of EFH information in accordance with the EFH provisions (§ 600.815(a)(10))'' to: ''Information on EFH to be included in accordance with the EFH provisions (§ 600.815(a)(10)). The language ''as a standalone chapter in a clearly noted section'' was removed because the EFH report tends to be a lengthy document that is included in the SAFE report that is comprised of a set of documents.

Paragraph (d)(3)(vi) was renumbered as paragraph (d)(3)(v), and revised to clarify by changing ''success of management measures'' to ''success and impacts of management measures.''

A new paragraph (d)(4) was added. It states: ''Transparency in the fishery management process is enhanced by complementing the SAFE report with the documentation of previous management actions taken by the Council and Secretary including a summary of the previous ACLs, ACTs, and accountability measures (AMs), and assessment of management uncertainty.''

Paragraph (d)(4) was renumbered as paragraph (d)(5).

Paragraph (d)(4)(i) was renumbered as paragraph (d)(5)(i), and revised by adding: ''Sources of information in the SAFE report should be referenced, unless the information is proprietary.''

Paragraph (d)(4)(ii) was renumbered as paragraph (d)(5)(ii).

Paragraph (e)(3) was revised for clarification by adding: ''Scientific information collections for stocks managed cooperatively by Federal and State governments should be coordinated with the appropriate state jurisdictions, to the extent practicable, to ensure harvest information is available for the management of stocks that utilize habitats in state and federal managed waters.''

VI. References Cited

- National Research Council of the National Academies (NRC). 2004. Improving the use of the ''best scientific information available'' standard in fisheries management. The National Academies Press, Washington, DC 105 pp.; *http://www.nap.edu/openbook.php*
- NOAA Office of the Chief Information Officer & High Performance Computing and Communications. 2006. National Oceanic and Atmospheric Administration Policy on Conflicts of Interest for Peer Review Subject to OMB Peer Review Bulletin. NOAA Memorandum, November 6, 2006; *http://www.cio.noaa.gov/Policy_Programs/NOAA_PRB_COI_Policy_110606.html.*
- Office of Management and Budget (OMB). 2004. Final Information Quality Bulletin for Peer Review. Executive Office of the President, Office of Management and Budget, memorandum M–05–03; December 16, 2004.

VII. Classification

The NMFS Assistant Administrator has determined that this action is consistent with the provisions of the MSA and other applicable law.

This action has been determined to be not significant for purposes of Executive Order 12866.

The Chief Council for Regulation of the Department of Commerce certified to the Chief Council for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the

proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

List of Subjects in 50 CFR Part 600

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: July 16, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons stated in the preamble, 50 CFR part 600 is to be amended as follows:

PART 600—MAGNUSON-STEVENS ACT PROVISIONS

■ 1. The authority citation for part 600 continues to read as follows:

Authority: 5 U.S.C. 561 and 16 U.S.C. 1801 *et seq.*

■ 2. Section 600.315 is revised to read as follows:

§ 600.315 National Standard 2—Scientific Information.

(a) *Standard 2.* Conservation and management measures shall be based upon the best scientific information available.

(1) Fishery conservation and management require high quality and timely biological, ecological, environmental, economic, and sociological scientific information to effectively conserve and manage living marine resources. Successful fishery management depends, in part, on the thorough analysis of this information, and the extent to which the information is applied for:

(i) Evaluating the potential impact that conservation and management measures will have on living marine resources, essential fish habitat (EFH), marine ecosystems, fisheries participants, fishing communities, and the nation; and

(ii) Identifying areas where additional management measures are needed.

(2) Scientific information that is used to inform decision making should include an evaluation of its uncertainty and identify gaps in the information. Management decisions should recognize the biological (e.g., overfishing), ecological, sociological, and economic (e.g., loss of fishery benefits) risks associated with the sources of uncertainty and gaps in the scientific information.

(3) Information-limited fisheries, commonly referred to as ''data-poor'' fisheries, may require use of simpler assessment methods and greater use of proxies for quantities that cannot be directly estimated, as compared to data-rich fisheries.

(4) Scientific information includes, but is not limited to, factual input, data, models, analyses, technical information, or scientific assessments. Scientific information includes data compiled directly from surveys or sampling programs, and models that are mathematical representations of reality constructed with primary data. The complexity of the model should not be the defining characteristic of its value; the data requirements and assumptions associated with a model should be commensurate with the resolution and accuracy of the available primary data. Scientific information includes established and emergent scientific information. Established science is scientific knowledge derived and verified through a standard scientific process that tends to be agreed upon often without controversy. Emergent science is relatively new knowledge that is still evolving and being verified, therefore, may potentially be uncertain and controversial. Emergent science should be considered more thoroughly, and scientists should be attentive to effective communication of emerging science.

(5) Science is a dynamic process, and new scientific findings constantly advance the state of knowledge. Best scientific information is, therefore, not static and ideally entails developing and following a research plan with the following elements: Clear statement of objectives; conceptual model that provides the framework for interpreting results, making predictions, or testing hypotheses; study design with an explicit and standardized method of collecting data; documentation of methods, results, and conclusions; peer review, as appropriate; and communication of findings.

(6) Criteria to consider when evaluating best scientific information are relevance, inclusiveness, objectivity, transparency and openness, timeliness, verification and validation, and peer review, as appropriate.

(i) *Relevance.* Scientific information should be pertinent to the current questions or issues under consideration and should be representative of the fishery being managed. In addition to the information collected directly about the fishery being managed, relevant information may be available about the same species in other areas, or about related species. For example, use of proxies may be necessary in data-poor situations. Analysis of related stocks or species may be a useful tool for inferring the likely traits of stocks for which stock-specific data are unavailable or are not sufficient to produce reliable estimates. Also, if management measures similar to those being considered have been introduced in other regions and resulted in particular behavioral responses from participants or business decisions from industry, such social and economic information may be relevant.

(ii) *Inclusiveness.* Three aspects of inclusiveness should be considered when developing and evaluating best scientific information:

(A) The relevant range of scientific disciplines should be consulted to encompass the scope of potential impacts of the management decision.

(B) Alternative scientific points of view should be acknowledged and addressed openly when there is a diversity of scientific thought.

(C) Relevant local and traditional knowledge (*e.g.,* fishermen's empirical knowledge about the behavior and distribution of fish stocks) should be obtained, where appropriate, and considered when evaluating the BSIA.

(iii) *Objectivity.* Scientific information should be accurate, with a known degree of precision, without addressable bias, and presented in an accurate, clear, complete, and balanced manner. Scientific processes should be free of undue nonscientific influences and considerations.

(iv) *Transparency and openness.* (A) The Magnuson-Stevens Act provides broad public and stakeholder access to the fishery conservation and management process, including access to the scientific information upon which the process and management measures are based. Public comment should be solicited at appropriate times during the review of scientific information. Communication with the public should be structured to foster understanding of the scientific process.

(B) Scientific information products should describe data collection methods, report sources of uncertainty or statistical error, and acknowledge other data limitations. Such products should explain any decisions to exclude data from analysis. Scientific products should identify major assumptions and uncertainties of analytical models. Finally, such products should openly acknowledge gaps in scientific information.

(v) *Timeliness.* Mandatory management actions should not be delayed due to limitations in the scientific information or the promise of future data collection or analysis. In some cases, due to time constraints,

results of important studies or monitoring programs may be considered for use before they are fully complete. Uncertainties and risks that arise from an incomplete study should be acknowledged, but interim results may be better than no results to help inform a management decision. Sufficient time should be allotted to audit and analyze recently acquired information to ensure its reliability. Data collection methods are expected to be subjected to appropriate review before providing data used to inform management decisions.

(A) For information that needs to be updated on a regular basis, the temporal gap between information collection and management implementation should be as short as possible, subject to regulatory constraints, and such timing concerns should be explicitly considered when developing conservation and management measures. Late submission of scientific information to the Council process should be avoided if the information has circumvented the review process. Data collection is a continuous process, therefore analysis of scientific information should specify a clear time point beyond which new information would not be considered in that analysis and would be reserved for use in subsequent analytical updates.

(B) Historical information should be evaluated for its relevance to inform the current situation. For example, some species' life history characteristics might not change over time. Other historical data (e.g., abundance, environmental, catch statistics, market and trade trends) provide time-series information on changes in fish populations, fishery participation, and fishing effort that may inform current management decisions.

(vi) *Verification and validation.* Methods used to produce scientific information should be verified and validated to the extent possible.

(A) *Verification* means that the data and procedures used to produce the scientific information are documented in sufficient detail to allow reproduction of the analysis by others with an acceptable degree of precision. External reviewers of scientific information require this level of documentation to conduct a thorough review.

(B) *Validation* refers to the testing of analytical methods to ensure that they perform as intended. Validation should include whether the analytical method has been programmed correctly in the computer software, the accuracy and precision of the estimates is adequate, and the estimates are robust to model assumptions. Models should be tested using simulated data from a population with known properties to evaluate how well the models estimate those characteristics and to correct for known bias to achieve accuracy. The concept of validation using simulation testing should be used, to the extent possible, to evaluate how well a management strategy meets management objectives.

(vii) *Peer review.* Peer review is a process used to ensure that the quality and credibility of scientific information and scientific methods meet the standards of the scientific and technical community. Peer review helps ensure objectivity, reliability, and integrity of scientific information. The peer review process is an organized method that uses peer scientists with appropriate and relevant expertise to evaluate scientific information. The scientific information that supports conservation and management measures considered by the Secretary or a Council should be peer reviewed, as appropriate. Factors to consider when determining whether to conduct a peer review and if so, the appropriate level of review, include the novelty and complexity of the scientific information to be reviewed, the level of previous review and the importance of the information to be reviewed to the decision making process. Routine updates based on previously reviewed methods require less review than novel methods or data. If formal peer review is not practicable due to time or resource constraints, the development and analysis of scientific information used in or in support of fishery management actions should be as transparent as possible, in accordance with paragraph (a)(6)(iv) of this section. Other applicable guidance on peer review can be found in the Office of Management and Budget Final Information Quality Bulletin for Peer Review.

(b) *Peer review process.* The Secretary and each Council may establish a peer review process for that Council for scientific information used to advise about the conservation and management of the fishery. 16 U.S.C. 1852(g)(1)(E). A peer review process is not a substitute for an SSC and should work in conjunction with the SSC (see § 600.310(b)(2)(v)(C)). This section provides guidance and standards that should be followed in order to establish a peer review process per Magnuson-Stevens Act section 302(g)(1)(E).

(1) The objective or scope of the peer review, the nature of the scientific information to be reviewed, and timing of the review should be considered when selecting the type of peer review to be used. The process established by the Secretary and Council should focus on providing review for information that has not yet undergone rigorous peer review, but that must be peer reviewed in order to provide reliable, high quality scientific advice for fishery conservation and management. Duplication of previously conducted peer review should be avoided.

(i) *Form of process.* The peer review process may include or consist of existing Council committees or panels if they meet the standards identified herein. The Secretary and Council have discretion to determine the appropriate peer review process for a specific information product. A peer review can take many forms, including individual letter or written reviews and panel reviews.

(ii) *Timing.* The peer review should, to the extent practicable, be conducted early in the process of producing scientific information or a work product, so peer review reports are available for the SSC to consider in its evaluation of scientific information for its Council and the Secretary. The timing will depend in part on the scope of the review. For instance, the peer review of a new or novel method or model should be conducted before there is an investment of time and resources in implementing the model and interpreting the results. The results of this type of peer review may contribute to improvements in the model or assessment.

(iii) *Scope of work.* The scope of work or charge (sometimes called the terms of reference) of any peer review should be determined in advance of the selection of reviewers. The scope of work contains the objectives of the peer review, evaluation of the various stages of the science, and specific recommendations for improvement of the science. The scope of work should be carefully designed, with specific technical questions to guide the peer review process; it should ask peer reviewers to ensure that scientific uncertainties are clearly identified and characterized, it should allow peer reviewers the opportunity to offer a broad evaluation of the overall scientific or technical product under review, as well as to make recommendations regarding areas of missing information, future research, data collection, and improvements in methodologies, and it must not change during the course of the peer review. The scope of work may not request reviewers to provide advice on policy or regulatory issues (e.g., amount of precaution used in decision-making) which are within the purview of the Secretary and the Councils, or to make formal fishing level

recommendations which are within the purview of the SSC.

(2) *Peer reviewer selection.* The selection of participants in a peer review should be based on expertise, independence, and a balance of viewpoints, and be free of conflicts of interest.

(i) *Expertise and balance.* Peer reviewers must be selected based on scientific expertise and experience relevant to the disciplines of subject matter to be reviewed. The group of reviewers that constitute the peer review should reflect a balance in perspectives, to the extent practicable, and should have sufficiently broad and diverse expertise to represent the range of relevant scientific and technical perspectives to complete the objectives of the peer review.

(ii) *Conflict of interest.* Peer reviewers who are federal employees must comply with all applicable federal ethics requirements. Potential reviewers who are not federal employees must be screened for conflicts of interest in accordance with the NOAA Policy on Conflicts of Interest for Peer Review Subject to OMB's Peer Review Bulletin or other applicable rules or guidelines.

(A) Under the NOAA policy, peer reviewers must not have any conflicts of interest with the scientific information, subject matter, or work product under review, or any aspect of the statement of work for the peer review. For purposes of this section, a conflict of interest is any financial or other interest which conflicts with the service of the individual on a review panel because it: could significantly impair the reviewer's objectivity, or could create an unfair competitive advantage for a person or organization.

(B) No individual can be appointed to a review panel if that individual has a conflict of interest that is relevant to the functions to be performed. For reviews requiring highly specialized expertise, the limited availability of qualified reviewers might result in an exception when a conflict of interest is unavoidable; in this situation, the conflict must be promptly and publicly disclosed. Conflicts of interest include, but are not limited to, the personal financial interests and investments, employer affiliations, and consulting arrangements, grants, or contracts of the individual and of others with whom the individual has substantial common financial interests, if these interests are relevant to the functions to be performed.

(iii) *Independence.* Peer reviewers must not have contributed or participated in the development of the work product or scientific information under review. For peer review of products of higher novelty or controversy, a greater degree of independence is necessary to ensure credibility of the peer review process. Peer reviewer responsibilities should rotate across the available pool of qualified reviewers or among the members on a standing peer review panel to prevent a peer reviewer from repeatedly reviewing the same scientific information, recognizing that, in some cases, repeated service by the same reviewer may be needed because of limited availability of specialized expertise.

(3) *Transparency.* A transparent process is one that ensures that background documents and reports from peer review are publicly available, subject to Magnuson-Stevens Act confidentiality requirements, and allows the public full and open access to peer review panel meetings. The evaluation and review of scientific information by the Councils, SSCs or advisory panels must be conducted in accordance with meeting procedures at § 600.135. Consistent with that section, public notice of peer review panel meetings should be announced in the **Federal Register** with a minimum of 14 days and with an aim of 21 days before the review to allow public comments during meetings. Background documents should be available for public review in a timely manner prior to meetings. Peer review reports describing the scope and objectives of the review, findings in accordance with each objective, and conclusions should be publicly available. Names and organizational affiliations of reviewers also should be publicly available.

(4) *Publication of the peer review process.* The Secretary will announce the establishment of a peer review process under Magnuson-Stevens Act section 302(g)(1)(E) in the **Federal Register** along with a brief description of the process. In addition, detailed information on such processes will be made publicly available on the Council's Web site, and updated as necessary.

(c) *SSC scientific evaluation and advice to the Council.* Each scientific and statistical committee shall provide its Council ongoing scientific advice for fishery management decisions, including recommendations for acceptable biological catch, preventing overfishing, maximum sustainable yield, achieving rebuilding targets, and reports on stock status and health, bycatch, habitat status, social and economic impacts of management measures, and sustainability of fishing practices. 16 U.S.C. 1852(g)(1)(B).

(1) SSC scientific advice and recommendations to its Council are based on scientific information that the SSC determines to meet the guidelines for best scientific information available as described in paragraph (a) of this section. SSCs may conduct peer reviews or evaluate peer reviews to provide clear scientific advice to the Council. Such scientific advice should attempt to resolve conflicting scientific information, so that the Council will not need to engage in debate on technical merits. Debate and evaluation of scientific information is the role of the SSC.

(2) An SSC member may participate in a peer review when such participation is beneficial to the peer review due to the expertise and institutional memory of that member, or beneficial to the Council's advisory body by allowing that member to make a more informed evaluation of the scientific information. Participation of an SSC member in a peer review should not impair the ability of that member to fulfill his or her responsibilities to the SSC.

(3) If an SSC as a body conducts a peer review established under Magnuson-Stevens Act section 302(g)(1)(E) or individual members of an SSC participate in such a peer review, the SSC members must meet the peer reviewer selection criteria as described in paragraph (b)(2) of this section. In addition, the financial disclosure requirements under § 600.235, Financial Disclosure for Councils and Council committees, apply. When the SSC as a body is conducting a peer review, it should strive for consensus and must meet the transparency guidelines under paragraphs (a)(6)(iv) and (b)(3) of this section. If consensus cannot be reached, minority viewpoints should be recorded.

(4) The SSC's evaluation of a peer review conducted by a body other than the SSC should consider the extent and quality of peer review that has already taken place. For Councils with extensive and detailed peer review processes (e.g., a process established pursuant to Magnuson-Stevens Act section 302(g)(1)(E)), the evaluation by the SSC of the peer reviewed information should not repeat the previously conducted and detailed technical peer review. However, SSCs must maintain their role as advisors to the Council about scientific information that comes from a peer review process. Therefore, the peer review of scientific information used to advise the Council, including a peer review process established by the Secretary and the Council under Magnuson-Stevens Act section

302(g)(1)(E), should be conducted early in the scientific evaluation process in order to provide the SSC with reasonable opportunity to consider the peer review report and make recommendations to the Council as required under Magnuson-Stevens Act section 302(g)(1)(B).

(5) If an SSC disagrees with the findings or conclusions of a peer review, in whole or in part, the SSC must prepare a report outlining the areas of disagreement, and the rationale and information used by the SSC for making its determination. This report must be made publicly available.

(6) Annual catch limits (ACLs) developed by a Council may not exceed its SSC's fishing level recommendations. 16 U.S.C. 1852(h)(6). Per the National Standard 1 Guidelines, the SSC fishing level recommendation that is most relevant to ACLs is acceptable biological catch (ABC), as both ACL and ABC are levels of annual catch (see § 600.310(b)(2)(v)(D)). The SSC is expected to take scientific uncertainty into account when making its ABC recommendation (§ 600.310(f)(4)). The ABC recommendation may be based upon input and recommendations from the peer review process. Any such peer review related to such recommendations should be conducted early in the process as described in paragraph (c)(4) of this section. The SSC should resolve differences between its recommendations and any relevant peer review recommendations per paragraph (c)(5) of this section.

(d) *SAFE Report.* The term SAFE (Stock Assessment and Fishery Evaluation) report, as used in this section, refers to a public document or a set of related public documents, that provides the Secretary and the Councils with a summary of scientific information concerning the most recent biological condition of stocks, stock complexes, and marine ecosystems in the fishery management unit (FMU), essential fish habitat (EFH), and the social and economic condition of the recreational and commercial fishing interests, fishing communities, and the fish processing industries. Each SAFE report must be scientifically based with appropriate citations of data sources and information. Each SAFE report summarizes, on a periodic basis, the best scientific information available concerning the past, present, and possible future condition of the stocks, EFH, marine ecosystems, and fisheries being managed under Federal regulation.

(1) The Secretary has the responsibility to ensure that SAFE reports are prepared and updated or supplemented as necessary whenever new information is available to inform management decisions such as status determination criteria (SDC), overfishing level (OFL), optimum yield, or ABC values (§ 600.310(c)). The SAFE report and any comments or reports from the SSC must be available to the Secretary and Council for making management decisions for each FMP to ensure that the best scientific information available is being used. The Secretary or Councils may utilize any combination of personnel from Council, State, Federal, university, or other sources to acquire and analyze data and produce the SAFE report.

(2) The SAFE report provides information to the Councils and the Secretary for determining annual catch limits (§ 600.310(f)(5)) for each stock in the fishery; documenting significant trends or changes in the resource, marine ecosystems, and fishery over time; implementing required EFH provisions (§ 600.815(a)(10)); and assessing the relative success of existing relevant state and Federal fishery management programs. The SAFE report should contain an explanation of information gaps and highlight needs for future scientific work. Information on bycatch and safety for each fishery should also be summarized. In addition, the SAFE report may be used to update or expand previous environmental and regulatory impact documents and ecosystem descriptions.

(3) Each SAFE report should contain the following scientific information when it exists:

(i) Information on which to base catch specifications and status determinations, including the most recent stock assessment documents and associated peer review reports, and recommendations and reports from the Council's SSC.

(A) A description of the SDC (e.g., maximum fishing mortality rate threshold and minimum stock size threshold for each stock or stock complex in the fishery) (§ 600.310(e)(2)).

(B) Information on OFL and ABC, preventing overfishing, and achieving rebuilding targets. Documentation of the data collection, estimation methods, and consideration of uncertainty in formulating catch specification recommendations should be included (§ 600.310(f)(2)). The best scientific information available to determine whether overfishing is occurring with respect to any stock or stock complex, whether any stock or stock complex is overfished, whether the rate or level of fishing mortality applied to any stock or stock complex is approaching the maximum fishing mortality threshold, and whether the size of any stock or stock complex is approaching the minimum stock size threshold; and

(C) The best scientific information available in support of management measures necessary to rebuild an overfished stock or stock complex (if any) in the fishery to a level consistent with producing the MSY in that fishery.

(ii) Information on sources of fishing mortality (both landed and discarded), including commercial and recreational catch and bycatch in other fisheries and a description of data collection and estimation methods used to quantify total catch mortality, as required by the National Standard 1 Guidelines (§ 600.310(i)).

(iii) Information on bycatch of non-target species for each fishery.

(iv) Information on EFH to be included in accordance with the EFH provisions (§ 600.815(a)(10)) .

(v) Pertinent economic, social, community, and ecological information for assessing the success and impacts of management measures or the achievement of objectives of each FMP.

(4) Transparency in the fishery management process is enhanced by complementing the SAFE report with the documentation of previous management actions taken by the Council or Secretary including a summary of the previous ACLs, ACTs, and accountability measures (AMs), and assessment of management uncertainty.

(5) To facilitate the use of the information in the SAFE report, and its availability to the Council, NMFS, and the public:

(i) The SAFE report should contain, or be supplemented by, a summary of the information and an index or table of contents to the components of the report. Sources of information in the SAFE report should be referenced, unless the information is proprietary.

(ii) The SAFE report or compilation of documents that comprise the SAFE report and index must be made available by the Council or NMFS on a readily accessible Web site.

(e) *FMP development.*—(1) FMPs must take into account the best scientific information available at the time of preparation. Between the initial drafting of an FMP and its submission for final review, new information often becomes available. This new information should be incorporated into the final FMP where practicable; but it is unnecessary to start the FMP process over again, unless the information indicates that drastic changes have occurred in the fishery that might require revision of the management objectives or measures.

(2) The fact that scientific information concerning a fishery is incomplete does not prevent the preparation and implementation of an FMP (see related §§ 600.320(d)(2) and 600.340(b)).

(3) An FMP must specify whatever information fishermen and processors will be required or requested to submit to the Secretary. Information about harvest within state waters, as well as in the EEZ, may be collected if it is needed for proper implementation of the FMP and cannot be obtained otherwise. Scientific information collections for stocks managed cooperatively by Federal and State governments should be coordinated with the appropriate state jurisdictions, to the extent practicable, to ensure harvest information is available for the management of stocks that utilize habitats in state and federal managed waters. The FMP should explain the practical utility of the information specified in monitoring the fishery, in facilitating inseason management decisions, and in judging the performance of the management regime; it should also consider the effort, cost, or social impact of obtaining it.

(4) An FMP should identify scientific information needed from other sources to improve understanding and management of the resource, marine ecosystem, the fishery, and fishing communities.

(5) The information submitted by various data suppliers should be comparable and compatible, to the maximum extent possible.

(6) FMPs should be amended on a timely basis, as new information indicates the necessity for change in objectives or management measures consistent with the conditions described in paragraph (d) of this section (SAFE reports). Paragraphs (e)(1) through (5) of this section apply equally to FMPs and FMP amendments.

[FR Doc. 2013–17422 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 78, No. 139
Friday, July 19, 2013

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 193

[Docket No.: FAA–2013–0375]

Technical Operations Safety Action Program (T–SAP) and Air Traffic Safety Action Program (ATSAP)

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of Proposed Order Designating Safety Information as Protected from Disclosure.

SUMMARY: The FAA is proposing that safety information provided to it under the T–SAP, established in Notice JO 7210.807 which will be incorporated in FAA Order JO 7200.20, *Voluntary Safety Reporting Programs,* and ATSAP, covered by FAA Order JO 7200.20, be designated by an FAA Order as protected from public disclosure in accordance with the provisions of 14 CFR part 193, *Protection of Voluntarily Submitted Information*. The designation is intended to encourage persons to voluntarily provide information to the FAA under the T–SAP and ATSAP, so the FAA can learn about and address aviation safety hazards of which it was unaware or more fully understand and implement corrective measures for events or safety issues known by it through other means. Under 49 U.S.C. 40123, *Protection of Voluntarily Submitted Information,* the FAA is required to protect information from disclosure to the public, including disclosure under the Freedom of Information Act (5 U.S.C. 552) or other laws, following the issuance of such Order.

DATES: Comments must be received on or before August 19, 2013.

ADDRESSES: You may send comments identified by docket number FAA–2013–0375 using any of the following methods: via mail to U.S. Department of Transportation, Docket Operations, M–30, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington DC 20590–0339; telephone (202) 366–9826. You must identify the FAA Docket No. FAA–2013–3075 at the beginning of your comments. You may also submit comments through this Web site at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Lisbeth Mack—Group Manager, ATO Safety Programs, Federal Aviation Administration, 490 L'Enfant Plaza, Suite 7200, Washington DC 20024 or via email at *lisbeth.mack@faa.gov* or phone at 202–385–4757.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify docket number FAA 2013–0375 and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2013–0375''. The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed Order. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of This Proposed Designation

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov*. Recently published rule-making documents can also be accessed through the FAA's Web site at *http://www.faa.gov/airports_airtraffic/air_traffic/publications*.

1. Background

Under Title 49 of the United States Code (49 U.S.C.), section 40123, certain voluntarily provided safety and security information is protected from disclosure in order to encourage persons to provide the information. The FAA must first issue an Order that specifies why the agency finds that the information should be protected in accordance with 49 U.S.C. 40123. The FAA's rules for implementing that section are in 14 CFR part 193. If the Administrator issues an Order designating information as protected under 49 U.S.C. 40123, that information will not be disclosed under the Freedom of Information Act (Title 5 of the United States Code (5 U.S.C.), section 552) or other laws, except as provided in 49 U.S.C. 40123, 14 CFR part 193, and the Order designating the information as protected. This Order is issued under part 193, section 193.11, which sets out the notice procedure for designating information as protected.

2. Applicability

This proposed designation is applicable to any FAA office that receives information covered under this designation from T–SAP, established in Notice JO 7210.807, and which will be incorporated in FAA Order JO 7200.20, *Voluntary Safety Reporting Programs,* or the ATSAP described in FAA Order JO 7200.20. The proposed designation would also apply to any other government agency that receives such information from the FAA. For any other government agency to receive T–SAP or ATSAP information covered under the proposed designation from the FAA, each such agency must first

stipulate, in writing, that it will abide by the provisions of part 193 and the Order designating T–SAP and ATSAP as protected from public disclosure under 14 CFR part 193.

3. Overview

a. *Qualified Participants.* Technical Operations employees who are covered under the collective bargaining agreement (CBA) between PASS and the FAA effective December 14, 2012, or its successor, and other employees identified in Notice JO 7210.807, which will be incorporated in Order JO 7200.20, are eligible to complete a T–SAP report for events that occur while acting in that capacity. Air Traffic employees who are covered under the CBA between NATCA and the FAA effective October 1, 2009 or its successor, Staff Support Specialists covered under the CBA between NATCA and FAA effective August 1, 2010 or its successor, Flight Services personnel covered under the CBA between NATCA and the FAA effective June 5, 2011, or its successor, employees covered under the CBA between NAGE Local R3–10 and the FAA dated May 24, 2007 or its successor, and others identified in FAA Order JO 7200.20 are eligible to file an ATSAP report for events that occur while acting in that capacity.

b. *Voluntarily-provided Information Protected from Disclosure Under the Proposed Designation.* Except for T–SAP or ATSAP reports that involve possible criminal conduct, substance abuse, controlled substances, alcohol, or intentional falsification, the following information would be protected from disclosure:

(1) The content of any report concerning an aviation safety or security matter that is submitted by a qualified participant under the T–SAP or ATSAP, that is accepted into either program, including the T–SAP or ATSAP report, and the name of the submitter of the report. Notwithstanding the foregoing, mandatory information about occurrences that are required to be reported under FAA Orders, Notices or guidance is not protected under this designation, unless the same information has also been submitted or reported under other procedures prescribed by the Agency. The exclusion is necessary to assure that the information protected under this designation has been voluntarily submitted. It also permits changes to FAA Orders, Notices and guidance without requiring a change to this designation.

(2) Any evidence gathered by the Event Review Committee during its investigation of a safety- or security-related event reported under T–SAP or ATSAP, including the T–SAP or ATSAP investigative file.

c. *Ways to Participate.* Individuals who are qualified participants register for, and submit a report into, the electronic reporting system.

d. *Duration of Voluntary Safety Reporting Programs.* These programs continue as long as provided for by Order, Notice, policy or a collective bargaining agreement.

4. Findings

The FAA designates information received from a T–SAP or ATSAP submission as protected under 49 U.S.C. 40123 and 14 CFR 193.7, based on the following findings:

a. *Summary of why the FAA finds that the information will be provided voluntarily.* The FAA finds that the information will be provided voluntarily. This finding is supported by the significant increase in reports of safety-related matters since the implementation of T–SAP and ATSAP. No covered individual is required to participate in the T–SAP, ATSAP, or other voluntary safety reporting program.

b. *Description of the type of information that may be voluntarily provided under the program and a summary of why the FAA finds that the information is safety-related.*

(1) The following types of reports are ordinarily submitted under the T–SAP or ATSAP:

i. *Noncompliance reports.* Noncompliance reports identify specific instances of a failure to follow FAA directives.

ii. *Aviation safety concern reports.* Aviation safety concerns that do not involve specific noncompliance with FAA directives. These may include, but are not limited to, potential safety events or perceived problems with policies, procedures, and equipment.

(2) Technical Operations personnel support the delivery and efficiency of flight services through maintenance of the National Airspace System facilities, systems and equipment. Reports submitted by these employees under T–SAP ordinarily involve matters or observations occurring during the performance of their job responsibilities, and therefore the information submitted is inherently safety related. Air Traffic personnel provide and support the provision of air traffic services at FAA facilities throughout the NAS. Reports submitted by these employees under ATSAP ordinarily involve occurrences or problems identified or experienced during the performance of their job responsibilities which directly affect safety.

c. *Summary of why the FAA finds that the disclosure of the information would inhibit persons from voluntarily providing that type of information.* The FAA finds that disclosure of the information would inhibit the voluntary provision of that type of information. Individuals are unwilling to voluntarily provide detailed information about safety events and concerns, including those that might involve their own failures to follow Agency directives and policies, if such information could be released publicly. If information is publicly disclosed, there is a strong likelihood that the information could be misused for purposes other than to address and resolve the reported safety concern. Unless the FAA can provide assurance that safety-related reports will be withheld from public disclosure, personnel will not participate in the programs.

d. *Summary of why the receipt of that type of information aids in fulfilling the FAA's safety responsibilities.* The FAA finds that receipt of information in T–SAP or ATSAP reports aids in fulfilling the FAA's safety responsibilities. Because of its capacity to provide early identification of needed safety improvements, this information offers significant potential for addressing hazards that could lead to incidents or accidents. In particular, one of the benefits of T–SAP and ATSAP is that they encourage the submission of narrative descriptions of occurrences that provide more detailed information than is otherwise available. The T–SAP and ATSAP produce safety-related data that is not available from any other source. Receipt of this previously unavailable information has provided the FAA with an improved basis for modifying procedures, policies, and regulations to improve safety and efficiency.

e. *Consistencies and inconsistencies with FAA safety responsibilities.* The FAA finds that withholding T–SAP and ATSAP information from public release is consistent with the FAA's safety responsibilities, because it encourages individuals to provide important safety information that it otherwise might not receive.

(1) Withholding T–SAP and ATSAP information from disclosure, as described in this designation, is consistent with the FAA's safety responsibilities. Without the Agency's ability to assure that the detailed information reported under these programs, which often explains why the event occurred or describes underlying problems, will not be disclosed, the

information will not be provided to the FAA. Individuals are concerned that public release of the information could result in potential misuses of the information that could affect them negatively. If the FAA does not receive the information, the FAA and the public will be deprived of the opportunity to make the safety improvements that receipt of the information otherwise enables. Corrective action under T–SAP and ATSAP can be accomplished without disclosure of protected information. For example, for acceptance under each program, the reporting individual must comply with ERC recommendations for corrective action, such as additional training. If the individual fails to complete corrective action in a manner satisfactory to all members of the ERC, the event may be referred to an appropriate office within the FAA for any additional investigation, reexamination, and/or action, as appropriate.

(2) The FAA may release T–SAP and ATSAP information submitted to the agency, as specified in Part 193 and this proposed Order. For example, to explain the need for changes in FAA policies, procedures, and regulations, the FAA may disclose de-identified, summarized information that has been derived from T–SAP and ATSAP reports or extracted from the protected information listed under paragraph 4b. The FAA may disclose de-identified, summarized T–SAP and ATSAP information that identifies a systemic problem in the National Airspace System, when a party needs to be advised of the problem in order to take corrective action. Under the current version of FAA Order JO 7200.20, reported events and possible violations may be subject to investigation, reexamination, and/or action. Although the report itself and the content of the report are not used as evidence, the FAA may use the knowledge of the event or possible violation to generate an investigation, and, in that regard, the information is not protected from disclosure. To withhold information from such limited release would be inconsistent with the FAA's safety responsibilities. In addition, reports that appear to involve possible criminal activity, substance abuse, controlled substances, alcohol, or intentional falsification will be referred to an appropriate FAA office for further handling. The FAA may use such reports for enforcement purposes, and will refer such reports to law enforcement agencies, if appropriate. To withhold information in these circumstances would be inconsistent with the agency's safety responsibilities because it could prevent, or at least diminish, the FAA's ability to effectively address egregious misconduct.

f. *Summary of how the FAA will distinguish information protected under part 193 from information the FAA receives from other sources.*

(1) All T–SAP and ATSAP reports are clearly labeled as such. Each individual must submit their own report.

5. Designation

The FAA designates the information described in paragraph 4b to be protected from disclosure in accordance with 49 U.S.C. 40123 and 14 CFR part 193.

Issued in Washington, DC, on July 10, 2013.

Michael P. Huerta,

Administrator, Federal Aviation Administration.

[FR Doc. 2013–17401 Filed 7–18–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA–1998–C–0381] (Formerly Docket No. 98C–0676)

Sensient Technologies Corporation; Withdrawal of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 8C0261) proposing that the color additive regulations be amended to provide for the safe use of External D&C Violet No. 2 in coloring externally applied drug products.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1309.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 24, 1998 (63 FR 45073), FDA announced that a color additive petition (CAP 8C0261) had been filed by Warner-Jenkinson Co., Inc. (now part of Sensient Cosmetic Technologies, a unit of Sensient Technologies Corporation), 107 Wade Ave., South Plainfield, NJ 07080. The petition proposed to amend the color additive regulations in 21 CFR part 74 *Listing of Color Additives Subject to Certification* to provide for the safe use of External D&C Violet No. 2 in coloring externally applied drug products. Sensient Technologies Corporation has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: July 16, 2013.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2013–17382 Filed 7–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172 and 182

[Docket Nos. FDA–2013–F–0700 and FDA–2013–P–0472]

Richard C. Theuer; Filing of Food Additive Petition and Citizen Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that Richard C. Theuer, Ph.D., has filed a petition proposing that the food additive regulations be amended to prohibit the use of carrageenan and salts of carrageenan in infant formula. In addition, the petitioner has submitted a citizen petition, under FDA regulations, requesting that we amend the generally recognized as safe (GRAS) regulations to prohibit the use of Chondrus extract (carrageenin) in infant formula.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1075.

SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that Richard C. Theuer, Ph.D., 7904 Sutterton Ct., Raleigh, NC 27615, has filed a food additive petition (FAP 3A4798; Docket No. FDA–2013–F–0700). The petition proposes to amend the food additive regulations in 21 CFR 172.620 and 172.626 to prohibit the use of carrageenan and salts of carrageenan in infant formula. In addition, Dr. Theuer has submitted a citizen petition, under 21 CFR 10.30, requesting that 21

CFR 182.7255 of the GRAS regulations be amended to prohibit the use of Chondrus extract (carrageenin) in infant formula (Docket No. FDA–2013–P–0472). (Carrageenin is an alternate name for carrageenan.)

Although the petitioner has submitted both a food additive petition and a citizen petition, for reasons of administrative efficiency, we may address all aspects of the petitions under the procedures established in section 409 of the FD&C Act and regulations issued under that section.

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 16, 2013.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2013–17330 Filed 7–18–13; 8:45 am]

BILLING CODE 4160–01–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 384

[Docket No. 2012–1 CRB Business Establishments II]

Determination of Rates and Terms for Business Establishment Services

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Proposed rule.

SUMMARY: The Copyright Royalty Judges are publishing for comment proposed regulations that set the rates and terms for the making of an ephemeral recording of a sound recording by a business establishment service for the period January 1, 2014, through December 31, 2018.

DATES: Comments and objections are due no later than August 19, 2013.

ADDRESSES: Comments and objections may be sent electronically to *crb@loc.gov.* In the alternative, send an original, five copies, and an electronic copy on a CD either by mail or hand delivery. Please do not use multiple means for transmission. Comments and objections may not be delivered by an overnight delivery service other than the U.S. Postal Service Express Mail. If by mail (including overnight delivery), comments and objections must be addressed to: Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977. If hand delivered by a private party, comments and objections must be brought between 8:30 a.m. and 5 p.m. to the Copyright Office Public Information Office, Library of Congress, James Madison Memorial Building, Room LM–401, 101 Independence Avenue SE., Washington, DC 20559–6000. If delivered by a commercial courier, comments and objections must be delivered between 8:30 a.m. and 4 p.m. to the Congressional Courier Acceptance Site located at 2nd and D Street NE., Washington, DC, and the envelope must be addressed to Copyright Royalty Board, Library of Congress, James Madison Memorial Building, LM–403, 101 Independence Avenue SE., Washington, DC 20559–6000.

FOR FURTHER INFORMATION CONTACT: LaKeshia Keys, Program Specialist, by telephone at (202) 707–7658 or email at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: In 1995, Congress enacted the Digital Performance in Sound Recordings Act, Public Law 104–39, which created an exclusive right for copyright owners of sound recordings, subject to certain limitations, to perform publicly sound recordings by means of certain digital audio transmissions. Among the limitations on the performance right was the creation of a statutory license for nonexempt, noninteractive digital subscription transmissions. 17 U.S.C. 114(d).

The scope of the section 114 statutory license was expanded in 1998 upon the passage of the Digital Millennium Copyright Act of 1998 (DMCA), Public Law 105–34, in order to allow for the public performance of a sound recording when made in accordance with the terms and rates of the statutory license, 17 U.S.C. 114(d), by a preexisting satellite digital audio radio service or as part of an eligible nonsubscription transmission. In addition to expanding the section 114 license, the DMCA also created a statutory license for the making of an ''ephemeral recording'' of a sound recording by certain transmitting organizations. 17 U.S.C. 112(e). This license allows entities that transmit performance of sound recordings to business establishments, pursuant to the limitations set forth in section 114(d)(1)(C)(iv), to make an ephemeral recording of a sound recording for a later transmission. *Id.* The license also provides a means by which a transmitting entity with a statutory license under section 114(f) can make more than one phonorecord permitted under the exemption set forth in section 112(a). 17 U.S.C. 112(e).

Chapter 8 of the Copyright Act requires the Copyright Royalty Judges (Judges) to conduct proceedings every five years to determine the rates and terms for ''the activities described in section 112(e)(1) relating to the limitation on exclusive rights specified by section 114(d)(1)(C)(iv).'' [1] 17 U.S.C. 801(b)(1), 804(b)(2). In accordance with section 804(b)(2), the Judges commenced a proceeding to set rates and terms for the making of ephemeral sound recordings by a business establishment service on January 5, 2007, 72 FR 584, and published in the **Federal Register** on March 27, 2008, final regulations setting those rates and terms. 73 FR 16199. Therefore, the next proceeding was to be commenced in January 2012. 17 U.S.C. 804(b)(2).

Accordingly, the Judges published a notice commencing the current proceeding and requesting interested parties to submit their petitions to participate. 77 FR 133 (Jan. 3, 2012). Petitions to Participate were received from: Pandora Media, Inc.; Music Choice; DMX, Inc.; Muzak LLC; Music Reports, Inc.; Clear Channel Broadcasting, Inc.; SoundExchange, Inc.; and Sirius XM Radio, Inc. The Judges set the timetable for the three-month negotiation period, *see* 17 U.S.C. 803(b)(3), and directed the participants to submit their written direct statements no later than November 16, 2012. Subsequently, the Judges granted the participants' request to extend the deadline to November 29, 2012, in order to allow the participants to finalize a settlement agreement. *See Order Granting Joint Motion for Extension of Time for Filing Written Direct Statements,* Docket No. 2012–1 CRB Business Establishments II (Nov. 14, 2012). On November 29, 2012, the Judges received a Motion to Adopt Settlement stating that all participants had reached a settlement obviating the need for a hearing.

Section 801(b)(7)(A) of the Copyright Act authorizes the Judges to adopt rates and terms negotiated by ''some or all of the participants in a proceeding at any time during the proceeding'' provided they are submitted to the Judges for approval. This section provides in part that the Judges must provide to both non-participants and participants to the rate proceeding who ''would be bound

[1] Prior to the enactment of the Copyright Royalty and Distribution Reform Act of 2004, which established the Copyright Royalty Judges, rates and terms for the statutory license under section 112(e) were set under the Copyright Arbitration Royalty Panel system, which was administered by the Librarian of Congress.

by the terms, rates, or other determination set by any agreement . . . an opportunity to comment on the agreement.'' 17 U.S.C. 801(b)(7)(A)(i). Participants to the proceeding may also ''object to [the agreement's] adoption as a basis for statutory terms and rates.'' *Id.* The Judges ''may decline to adopt the agreement as a basis for statutory terms and rates for participants that are not parties to the agreement,'' only ''if any participant [to the proceeding] objects to the agreement and the [Judges] conclude, based on the record before them if one exists, that the agreement does not provide a reasonable basis for setting statutory terms or rates.'' 17 U.S.C. 801(b)(7)(A)(ii).

Rates and terms adopted pursuant to section 801(b)(7)(A) are binding on all copyright owners of sound recordings and business establishment services making an ephemeral recording of a sound recording for the period January 1, 2014, through December 31, 2018.

As noted above, the public may comment and object to any or all of the proposed regulations contained in this notice. Such comments and objections must be submitted no later than August 19, 2013.

List of Subjects in 37 CFR Part 384

Copyright, Digital audio transmissions, Ephemeral recordings, Performance right, Sound recordings.

Proposed Regulations

For the reasons set forth in the preamble, the Copyright Royalty Judges propose to amend part 384 of chapter III of title 37 of the Code of Federal Regulations to read as follows:

PART 384—RATES AND TERMS FOR THE MAKING OF EPHEMERAL RECORDINGS BY BUSINESS ESTABLISHMENT SERVICES

■ 1. The authority citation for part 384 continues to read as follows:

Authority: 17 U.S.C. 112(e), 801(b)(1).

§ 384.1 [Amended]

■ 2. Section 384.1 is amended as follows:

■ a. In paragraph (a), by removing ''§ 384.2(a)'' and adding ''§ 384.2'' in its place, and by removing ''2009–1013'' and adding ''January 1, 2014, through December 31, 2018'' in its place;

■ b. In paragraph (b), by removing ''licenses set forth in 17 U.S.C. 112'' and adding ''license set forth in 17 U.S.C. 112(e)'' in its place; and

■ c. In paragraph (c), by removing ''services'' and adding ''Licensees'' in its place.

■ 3. Section 384.2 is amended by revising the definition for ''*Copyright Owner''* to read as follows:

§ 384.2 Definitions.

* * * * *

Copyright Owners are sound recording copyright owners who are entitled to royalty payments made under this part pursuant to the statutory license under 17 U.S.C. 112(e).

* * * * *

§ 384.3 [Amended]

■ 4. Section 384.3 is amended as follows:

■ a. In paragraph (a), by removing ''service pursuant to the limitation on exclusive rights specified by 17 U.S.C. 114(d)(1)(C)(iv)'' and adding ''Business Establishment Service'' in its place and removing ''10%'' and adding ''12.5%'' in its place; and

■ b. In paragraph (b), by removing ''$10,000 for each calendar year'' and adding ''$10,000 for each calendar year of the License Period'' in its place.

■ 5. Section 384.4 is amended as follows:

■ a. By revising the paragraph heading for paragraph (a);

■ b. In paragraph (b)(2)(i), by removing ''condition precedent in paragraph (b)(2) of this section'' and adding ''condition precedent in this paragraph (b)(2)'' in its place, and by removing ''authorized such Collective'' and adding ''authorized the Collective'' in its place;

■ c. By revising paragraphs (c) through (e);

■ d. By revising introductory text of paragraph (f);

■ e. In paragraph (f)(2), by removing ''facsimile number'' and adding ''facsimile number (if any)'' in its place, and by removing ''individual or individuals'' and adding ''person'' in its place;

■ f. In paragraph (f)(3), by removing ''handwritten'';

■ g. In paragraph (f)(3)(i), by removing ''a corporation'' and adding ''corporation'' in its place;

■ h. In paragraph (f)(6), by removing ''a corporation'' and adding ''corporation'' in its place;

■ i. In paragraph (f)(8), by removing ''if the Licensee is a corporation or partnership,'';

■ j. By revising paragraphs (g) and (h); and

■ k. By removing paragraph (i).

The revisions read as follows:

§ 384.4 Terms for making payment of royalty fees and statements of account.

(a) *Payment to the Collective.* * * * * * * * * *

(c) *Monthly payments.* A Licensee shall make any payments due under § 384.3(a) on a monthly basis on or before the 45th day after the end of each month for that month. All monthly payments shall be rounded to the nearest cent.

(d) *Minimum payments.* A Licensee shall make any minimum payment due under § 384.3(b) by January 31 of the applicable calendar year, except that payment by a Licensee that has not previously made Ephemeral Recordings pursuant to the license under 17 U.S.C. 112(e) shall be due by the 45th day after the end of the month in which the Licensee commences to do so.

(e) *Late payments.* A Licensee shall pay a late fee of 1.0% per month, or the highest lawful rate, whichever is lower, if either or both a required payment or statement of account for a required payment is received by the Collective after the due date. Late fees shall accrue from the due date until both the payment and statement of account are received by the Collective.

(f) *Statements of account.* For any part of the License Period during which a Licensee operates a Business Establishment Service, at the time when a minimum payment is due under paragraph (d) of this section, and by 45 days after the end of each month during the period, the Licensee shall deliver to the Collective a statement of account containing the information set forth in this paragraph (f) on a form prepared, and made available to Licensees, by the Collective. In the case of a minimum payment, or if a payment is owed for such month, the statement of account shall accompany the payment. A statement of account shall contain only the following information:

* * * * *

(g) *Distribution of royalties.* (1) The Collective shall promptly distribute royalties received from Licensees directly to Copyright Owners, or their designated agents, that are entitled to such royalties. The Collective shall only be responsible for making distributions to those Copyright Owners or their designated agents who provide the Collective with such information as is necessary to identify the correct recipient. The Collective shall distribute royalties on a basis that values all Ephemeral Recordings by a Licensee equally based upon the information provided under the reports of use requirements for Licensees contained in § 370.4 of this chapter.

(2) If the Collective is unable to locate a Copyright Owner entitled to a distribution of royalties under paragraph (g)(1) of this section within 3 years from the date of payment by a Licensee, such royalties shall be handled in accordance with § 384.8.

(h) *Retention of records.* Books and records of a Licensee and of the Collective relating to payments of and distributions of royalties shall be kept for a period of not less than the prior 3 calendar years.

§ 384.5 [Amended]

■ 6. Section 384.5 is amended as follows:

■ a. In paragraph (a), by removing ''part'' and adding ''section'' in its place, and by removing ''account, any information'' and adding ''account and any information'' in its place;

■ b. In paragraph (b), by removing ''The Collective shall have'' and adding ''The party claiming the benefit of this provision shall have'' in its place;

■ c. In paragraph (c), by removing ''activities directly related thereto'' and adding ''activities related directly thereto'' in its place;

■ d. In paragraph (d)(1), by removing ''work, require access to the records'' and adding ''work require access to Confidential Information'' in its place;

■ e. In paragraph (d)(2), by removing ''Collective committees'' and adding ''the Collective committees'' in its place, and by removing ''confidential information'' and adding ''Confidential Information'' in its place each place it appears;

■ f. In paragraph (d)(3), by removing ''respect to the verification of a Licensee's royalty payments'' and adding ''respect to verification of a Licensee's statement of account'' in its place;

■ g. In paragraph (d)(4), by removing ''Copyright owners whose works'' and adding ''Copyright Owners, including their designated agents, whose works'' in its place, by removing '', or agents thereof'', and by removing ''confidential information'' and adding ''Confidential Information'' in its place; and

■ h. In paragraph (e), by removing ''to safeguard all Confidential Information'' and adding ''to safeguard against unauthorized access to or dissemination of any Confidential Information'' in its place, and by removing ''belonging to such Collective'' and adding ''belonging to the Collective'' in its place.

■ 7. Section 384.6 is amended by revising paragraph (d) to read as follows:

§ 384.6 Verification of royalty payments.

* * * * *

(d) *Acquisition and retention of report.* The Licensee shall use commercially reasonable efforts to obtain or to provide access to any relevant books and records maintained by third parties for the purpose of the audit. The Collective shall retain the report of the verification for a period of not less than 3 years.

* * * * *

■ 8. Section 384.7 is amended as follows:

■ a. In paragraph (a), by removing ''Provided'' and adding ''provided'' in its place; and

■ b. By revising paragraph (d).

The revision reads as follows:

§ 384.7 Verification of royalty distributions.

* * * * *

(d) *Acquisition and retention of record.* The Collective shall use commercially reasonable efforts to obtain or to provide access to any relevant books and records maintained by third parties for the purpose of the audit. The Copyright Owner requesting the verification procedure shall retain the report of the verification for a period of not less than 3 years.

* * * * *

■ 9. Section 384.8 is revised to read as follows:

§ 384.8 Unclaimed funds.

If the Collective is unable to identify or locate a Copyright Owner who is entitled to receive a royalty distribution under this part, the Collective shall retain the required payment in a segregated trust account for a period of 3 years from the date of distribution. No claim to such distribution shall be valid after the expiration of the 3-year period. After expiration of this period, the Collective may apply the unclaimed funds to offset any costs deductible under 17 U.S.C. 114(g)(3). The foregoing shall apply notwithstanding the common law or statutes of any State.

Dated: July 12, 2013.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2013–17243 Filed 7–18–13; 8:45 am]

BILLING CODE 1410–72–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R01–OAR–2013–0020; FRL–9834–7]

Approval and Promulgation of Air Quality Implementation Plans; Connecticut; Redesignation of Connecticut Portion of the New York-New Jersey-Connecticut Nonattainment Area to Attainment of the 1997 Annual and 2006 24-Hour Standards for Fine Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve the State of Connecticut's June 22, 2012 request to redesignate the Connecticut portion of the New York-N. New Jersey-Long Island, NY-NJ-CT fine particle ($PM_{2.5}$) area (i.e., New Haven and Fairfield Counties; herein called the ''Southwestern CT Area'' or ''the Area'') from nonattainment to attainment for the 1997 annual National Ambient Air Quality Standards (NAAQS or standard), as well as for the 2006 24-hour $PM_{2.5}$ NAAQS. As part of these proposed approvals, EPA proposes to approve (1) a State Implementation Plan (SIP) revision containing a 10-year maintenance plan for the Area; (2) a 2007 base-year emissions inventory for the Area; and (3) new motor vehicle emissions budgets (MVEBs) for the years 2017 and 2025 that are contained in the 10-year $PM_{2.5}$ maintenance plan for the Area.

In addition, in the course of proposing to approve Connecticut's request to redesignate the Southwestern CT Area, EPA addresses a number of additional issues, including the effects of two decisions of the United States Court of Appeals for the District of Columbia (D.C. Circuit Court): (1) The Court's August 21, 2012 decision to vacate and remand to EPA the Cross-State Air Pollution Control Rule (CSAPR), and (2) the Court's January 4, 2013 decision to remand to EPA two final rules implementing the 1997 $PM_{2.5}$ standard.

This action is being taken in accordance with the Clean Air Act (CAA).

DATES: Written comments must be received on or before August 19, 2013.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R01–OAR–2013–0020 by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *Email: arnold.anne@epa.gov*

3. *Fax:* (617) 918–0047.

4. *Mail:* ''Docket Identification Number EPA–R01–OAR–2013–0020,'' Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100 (mail code: OEP05–2), Boston, MA 02109–3912.

5. *Hand Delivery or Courier.* Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA 02109–3912. Such deliveries are only

accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R01–OAR–2013–0020. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *www.regulations.gov* or email, information that you consider to be CBI or otherwise protected. The *www.regulations.gov* Web site is an ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Alison C. Simcox, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109—3912, telephone number (617) 918–1684, fax number (617) 918–0684, email *simcox.alison@epa.gov.*

In addition to the publicly available docket materials available for inspection electronically in the Federal Docket Management System at *www.regulations.gov,* and the hard copy available at the Regional Office, which are identified in the **ADDRESSES** section of this **Federal Register**, copies of the state submittal are also available for public inspection during normal business hours, by appointment at the State Air Agency: Bureau of Air Management, Department of Energy and Environmental Protection, State Office Building, 79 Elm Street, Hartford, CT 06106–1630.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Table of Contents

I. What should I consider as I prepare my comments for EPA?

When submitting comments, remember to:

1. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date, and page number).

2. Follow directions—EPA may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

4. Describe any assumptions and provide any technical information and/or data that you used.

5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

6. Provide specific examples to illustrate your concerns, and suggest alternatives.

7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

8. Make sure to submit your comments by the comment period deadline identified.

II. What is the background for the proposal?

A. General Background

On June 22, 2012, the Connecticut Department of Energy and Environmental Protection (CT DEEP)

submitted a request to EPA to redesignate the Connecticut portion of the New York-N. New Jersey-Long Island, NY-NJ-CT fine particle ($PM_{2.5}$) area (the Southwestern CT Area comprising New Haven and Fairfield Counties) to attainment for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, and for EPA approval of the state implementation plan (SIP) revision containing an emissions inventory and a maintenance plan for the area.

Fine particulate pollution is emitted directly from a source (primary $PM_{2.5}$) or is formed secondarily through chemical reactions in the atmosphere involving precursor pollutants (nitrogen oxides (NO_X), sulfur dioxides (SO_2), volatile organic compounds (VOC), and ammonia (NH_3)) emitted from a variety of sources. For example, sulfates are formed from SO_2 emissions from power plants and industrial facilities. Nitrates are formed from combustion emissions of NO_X from power plants, mobile sources, and other combustion sources.

The CAA establishes a process for air-quality management through the NAAQS. The first air quality standards for $PM_{2.5}$ were promulgated on July 18, 1997 (62 FR 38652). EPA promulgated an annual standard at a level of 15 micrograms per cubic meter ($\mu g/m^3$) of ambient air, based on a three-year average of the annual mean $PM_{2.5}$ concentrations at each monitoring site. In the same rulemaking, EPA promulgated a 24-hour $PM_{2.5}$ standard of 65 $\mu g/m^3$, based on a three-year average of the annual 98th percentile of 24-hour concentrations at each monitoring site.

On January 5, 2005 (70 FR 944), EPA designated the New York-N. New Jersey-Long Island, NY-NJ-CT area (also referred to as the New York Metropolitan Area), which includes the Southwestern CT Area, as nonattainment for the 1997 $PM_{2.5}$ NAAQS. See 70 FR 944 for a listing of all counties included in the tri-state nonattainment area.

On October 17, 2006 (71 FR 61144), EPA issued the 2006 $PM_{2.5}$ NAAQS. The 2006 NAAQS retained the annual $PM_{2.5}$ standard at 15 $\mu g/m^3$, but revised the 24-hour standard to 35 $\mu g/m^3$, based on a three-year average of the annual 98th percentile of the 24-hour $PM_{2.5}$ concentrations. However, petitioners challenged EPA's decision to retain the annual standard (but did not challenge the 2006 24-hour $PM_{2.5}$ standard). On February 24, 2009, the U.S. Court of Appeals for the D.C. Circuit remanded the annual $PM_{2.5}$ standard to the Agency for reconsideration. *See American Farm Bureau Federation and National Pork Producers Council, et al.* v. *EPA,* 559 F.3d 512 (D.C. Cir. 2009).

On November 13, 2009 (74 FR 58688), EPA published designations for the 24-hour standard established in 2006, designating the same New York Metropolitan Area (including the Southwestern CT Area) as nonattainment for this standard. In the November 2009 action, EPA clarified the designations for the NAAQS promulgated in 1997, stating that the New York Metropolitan Area remained designated nonattainment for the 1997 annual $PM_{2.5}$ NAAQS, but was designated attainment for the 1997 24-hour NAAQS. Therefore, today's action does not address attainment of the 1997 24-hour $PM_{2.5}$ NAAQS.

Today's action also does not address attainment of the remanded 2006 annual standard. However, given that the 1997 and 2006 annual standards are essentially identical, attainment of the 1997 annual standard would also indicate attainment of the remanded 2006 annual standard. Therefore, today's action addresses attainment of the 1997 annual standard and the 2006 24-hour standard.

On November 15, 2010, EPA determined that the entire New York Metropolitan Area had attained the 1997 annual $PM_{2.5}$ standard (75 FR 69589). This determination of attainment was based upon complete, quality-assured and certified ambient air-quality data for the 2007–2009 monitoring period. Subsequently, on December 31, 2012, EPA determined that the entire New York Metropolitan Area had also attained the 2006 24-hour $PM_{2.5}$ standard (77 FR 76867). This determination of attainment was based upon complete, quality-assured and certified ambient air-quality data for the 2007–2009, 2008–2010, and 2009–2011 monitoring periods. In addition, $PM_{2.5}$ monitoring data for 2012 indicate continued attainment of both standards. These determinations of attainment suspended the requirements for Connecticut to submit an attainment demonstration, associated reasonably available control measures, reasonable further progress (RFP), contingency measures, and other planning SIPs related to attainment of the 1997 annual or 2006 24-hour $PM_{2.5}$ NAAQS for as long as the Southwestern CT Area continues to attain these standards.

The CT DEEP redesignation request includes a maintenance plan designed to ensure continued compliance with both the 1997 annual and 2006 24-hour $PM_{2.5}$ standards through the year 2025. On December 14, 2012, EPA issued a new annual standard of 12 $\mu g/m^3$. Today's action does not address the 2012 standard.

B. Effect of the August 21, 2012 D.C. Circuit Decision Regarding EPA's CSAPR

On May 12, 2005, EPA published the Clean Air Interstate Rule (CAIR), which requires significant reductions in emissions of SO_2 and NO_X from electric generating units (EGUs) to limit the interstate transport of these pollutants and the ozone and fine particulate matter they form in the atmosphere. *See* 76 FR 70093. The D.C. Circuit Court initially vacated CAIR, *North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008), but ultimately remanded that rule to EPA without vacatur to preserve the environmental benefits provided by CAIR, *North Carolina* v. *EPA,* 550 F.3d 1176, 1178 (D.C. Cir. 2008).

The Cross State Air Pollution Rule (CSAPR) included regulatory changes to sunset (i.e., discontinue) CAIR and the CAIR Federal Implementation Plans (FIPs) for control periods in 2012 and beyond. *See* 76 FR 48322. On December 30, 2011, the D.C. Circuit issued an order addressing the status of CSAPR and CAIR in response to motions filed by numerous parties seeking a stay of CSAPR pending judicial review. In that order, the Court stayed CSAPR pending resolution of the petitions for review of that rule in *EME Homer City Generation, L.P.* v. *EPA* (No. 11–1302 and consolidated cases). The Court also indicated that EPA was expected to continue to administer CAIR in the interim until judicial review of CSAPR was completed.

On August 21, 2012, the D.C. Circuit issued *EME Homer City Generation, L.P.* v. *EPA,* 696 F.3d 7 (D.C. Cir. 2012), which vacated and remanded CSAPR and ordered EPA to continue administering CAIR ''pending . . . development of a valid replacement.'' *EME Homer City* at 38. The D.C. Circuit denied all petitions for rehearing on January 24, 2013. On March 29, 2013, the U.S. Solicitor General petitioned the Supreme Court to review the D.C. Circuit Court's decision on CSAPR. On June 24, 2013, the Supreme Court granted the petition to review the decision. The Supreme Court's decision to review the case does not alter the current status of CAIR or CSAPR.

Connecticut's submittal and EPA modeling demonstrate that attainment of the 1997 annual and 2006 24-hour $PM_{2.5}$ standards will be maintained with or without the implementation of CAIR or CSAPR. To the extent that attainment is due to emission reductions associated with CAIR, EPA is here determining that those reductions are sufficiently

permanent and enforceable for purposes of CAA sections 107(d)(3)(E)(iii) and 175A.

As directed by the D.C. Circuit, CAIR remains in place and enforceable until EPA promulgates a valid replacement rule to substitute for CAIR. Connecticut's SIP revision lists CAIR as a control measure (Regulations of Connecticut State Agencies (RCSA) section 22a–174–22c) that was adopted by the State in September 2007 with an effective date of May 1, 2009. CAIR was, thus, in place and achieving emission reductions when the New York Metropolitan Area began monitoring attainment of the 1997 annual $PM_{2.5}$ standard during the 2007–2009 period, and of the 2006 24-hour $PM_{2.5}$ standards during the same period. The quality-assured, certified monitoring data continues to show the area in attainment with the 1997 and 2006 $PM_{2.5}$ standards through 2012.

In addition, modeling conducted by EPA during the CSAPR rulemaking process also demonstrates that the Southwestern CT Area will have $PM_{2.5}$ levels below the 1997 annual and 2006 24-hour $PM_{2.5}$ standards in both 2012 and 2014 without taking into account emissions reductions from CAIR or CSAPR. See ''Air Quality Modeling Final Rule Technical Support Document'', App. B, B–18, B–19. This modeling is available in the docket for this proposed redesignation action.

In sum, neither the current status of CAIR nor the current status of CSAPR affects any of the criteria for proposed approval of this redesignation request for the Southwestern CT Area.

C. Effect of the January 4, 2013 D.C. Circuit Decision Regarding $PM_{2.5}$ Implementation Under Subpart 4

1. Background

As discussed above, on January 4, 2013, in *Natural Resources Defense Council* v. *EPA,* the D.C. Circuit remanded to EPA the ''Final Clean Air Fine Particle Implementation Rule'' (72 FR 20586, April 25, 2007) and the ''Implementation of the New Source Review (NSR) Program for Particulate Matter Less than 2.5 Micrometers ($PM_{2.5}$)'' final rule (73 FR 28321, May 16, 2008) (collectively, ''1997 $PM_{2.5}$ Implementation Rule''). 706 F.3d 428 (D.C. Cir. 2013). The Court found that EPA erred in implementing the 1997 $PM_{2.5}$ NAAQS pursuant to the general implementation provisions of subpart 1 of Part D of Title I of the CAA, rather than the particulate-matter-specific provisions of subpart 4 of Part D of Title I. Although the Court's ruling did not directly address the 2006 $PM_{2.5}$ standard, EPA is taking into account the Court's position on subpart 4 and the 1997 $PM_{2.5}$ standard in evaluating redesignations for the 2006 standard.

2. Proposal on This Issue

EPA is proposing to determine that the Court's January 4, 2013 decision does not prevent EPA from redesignating the Southwestern CT Area to attainment. Even in light of the Court's decision, redesignation for this area is appropriate under the CAA and EPA's longstanding interpretations of the CAA's provisions regarding redesignation. EPA first explains its longstanding interpretation that requirements that are imposed, or that become due, after a complete redesignation request is submitted for an area that is attaining the standard, are not applicable for purposes of evaluating a redesignation request. Second, EPA then shows that, even if EPA applies the subpart 4 requirements to Connecticut's redesignation request and disregards the provisions of its 1997 $PM_{2.5}$ implementation rule recently remanded by the Court, the state's request for redesignation of this area still qualifies for approval. EPA's discussion takes into account the effect of the Court's ruling on the area's maintenance plan, which EPA views as approvable when subpart 4 requirements are considered.

a. Applicable Requirements for Purposes of Evaluating the Redesignation Request

With respect to the 1997 $PM_{2.5}$ Implementation Rule, the Court's January 4, 2013 ruling rejected EPA's reasons for implementing the $PM_{2.5}$ NAAQS solely in accordance with the provisions of subpart 1, and remanded that matter to EPA, so that it could address implementation of the 1997 $PM_{2.5}$ NAAQS under subpart 4 of Part D of the CAA, in addition to subpart 1. For the purposes of evaluating Connecticut's redesignation request for the Southwestern CT Area, to the extent that implementation under subpart 4 would impose additional requirements for areas designated nonattainment, EPA believes that those requirements are not ''applicable'' for the purposes of CAA section 107(d)(3)(E), and, thus, EPA is not required to consider subpart 4 requirements with respect to this redesignation request. Under its longstanding interpretation of the CAA, EPA has interpreted section 107(d)(3)(E) to mean, as a threshold matter, that the part D provisions which are ''applicable'' and which must be approved in order for EPA to redesignate an area include only those which came due prior to a state's submittal of a complete redesignation request. *See* ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (Calcagni memorandum). *See also* ''State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) on or after November 15, 1992,'' Memorandum from Michael Shapiro, Acting Assistant Administrator, Air and Radiation, September 17, 1993 (Shapiro memorandum); Final Redesignation of Detroit-Ann Arbor, (60 FR 12459, 12465–66, March 7, 1995); Final Redesignation of St. Louis, Missouri, (68 FR 25418, 25424–27, May 12, 2003); *Sierra Club* v. *EPA,* 375 F.3d 537, 541 (7th Cir. 2004) (upholding EPA's redesignation rulemaking applying this interpretation and expressly rejecting Sierra Club's view that the meaning of ''applicable'' under the statute is ''whatever should have been in the plan at the time of attainment rather than whatever actually was in the plan and already implemented or due at the time of attainment'').[1] In this case, at the time that Connecticut submitted its redesignation request, requirements under subpart 4 were not due.

EPA's view that, for purposes of evaluating the Southwestern CT Area redesignation, the subpart 4 requirements were not due at the time the State submitted the redesignation request is in keeping with the EPA's interpretation of subpart 2 requirements for subpart 1 ozone areas redesignated subsequent to the D.C. Circuit's decision in *South Coast Air Quality Mgmt. Dist.* v. *EPA,* 472 F.3d 882 (D.C. Cir. 2006). In *South Coast,* the Court found that EPA was not permitted to implement the 1997 8-hour ozone standard solely under subpart 1, and held that EPA was required under the statute to implement the standard under the ozone-specific requirements of subpart 2 as well. Subsequent to the *South Coast* decision, in evaluating and acting upon redesignation requests for the 1997 8-hour ozone standard that were submitted to EPA for areas under subpart 1, EPA applied its longstanding interpretation of the CAA that ''applicable requirements,'' for purposes

[1] Applicable requirements of the CAA that come due subsequent to the area's submittal of a complete redesignation request remain applicable until a redesignation is approved, but are not required as a prerequisite to redesignation. Section 175A(c) of the CAA.

of evaluating a redesignation, are those that had been due at the time the redesignation request was submitted. *See, e.g.,* Proposed Redesignation of Manitowoc County and Door County Nonattainment Areas (75 FR 22047, 22050, April 27, 2010). In those actions, EPA therefore did not consider subpart 2 requirements to be ''applicable'' for the purposes of evaluating whether the area should be redesignated under section 107(d)(3)(E).

EPA's interpretation derives from the provisions of CAA Section 107(d)(3). Section 107(d)(3)(E)(v) states that, for an area to be redesignated, a state must meet ''all requirements 'applicable' to the area under section 110 and part D.'' Section 107(d)(3)(E)(ii) provides that the EPA must have fully approved the ''applicable'' SIP for the area seeking redesignation. These two sections read together support EPA's interpretation of ''applicable'' as only those requirements that came due prior to submission of a complete redesignation request. First, holding states to an ongoing obligation to adopt new CAA requirements that arose after the state submitted its redesignation request, in order to be redesignated, would make it problematic or impossible for EPA to act on redesignation requests in accordance with the 18-month deadline Congress set for EPA action in section 107(d)(3)(D). If ''applicable requirements'' were interpreted to be a continuing flow of requirements with no reasonable limitation, states, after submitting a redesignation request, would be forced continuously to make additional SIP submissions that in turn would require EPA to undertake further notice-and-comment rulemaking actions to act on those submissions. This would create a regime of unceasing rulemaking that would delay action on the redesignation request beyond the 18-month timeframe provided by the Act for this purpose.

Second, a fundamental premise for redesignating a nonattainment area to attainment is that the area has attained the relevant NAAQS due to emission reductions from existing controls. Thus, an area for which a redesignation request has been submitted would have already attained the NAAQS as a result of satisfying statutory requirements that came due prior to the submission of the request. Absent a showing that unadopted and unimplemented requirements are necessary for future maintenance, it is reasonable to view the requirements applicable for purposes of evaluating the redesignation request as including only those SIP requirements that have already come due. These are the requirements that led to attainment of the NAAQS. To require, for redesignation approval, that a state also satisfy additional SIP requirements coming due after the state submits its complete redesignation request, and while EPA is reviewing it, would compel the state to do more than is necessary to attain the NAAQS, without a showing that the additional requirements are necessary for maintenance.

In the context of this redesignation, the timing and nature of the Court's January 4, 2013 decision in *NRDC* v. *EPA* compound the consequences of imposing requirements that come due after the redesignation request is submitted. The State submitted its redesignation request on June 22, 2012, but the Court did not issue its decision remanding EPA's 1997 $PM_{2.5}$ implementation rule concerning the applicability of the provisions of subpart 4 until January 2013.

To require the State's fully-completed and pending redesignation request for the 2006 $PM_{2.5}$ standard to comply now with requirements of subpart 4 that the Court announced only in its January, 2013 decision on the 1997 $PM_{2.5}$ implementation rule, would be to give retroactive effect to such requirements when the State had no notice that it was required to meet them. The D.C. Circuit recognized the inequity of this type of retroactive impact in *Sierra Club* v. *Whitman,* 285 F.3d 63 (D.C. Cir. 2002),[2] where it upheld the District Court's ruling refusing to make retroactive EPA's determination that the St. Louis area did not meet its attainment deadline. In that case, petitioners urged the Court to make EPA's nonattainment determination effective as of the date that the statute required, rather than the later date on which EPA actually made the determination. The Court rejected this view, stating that applying it ''would likely impose large costs on States, which would face fines and suits for not implementing air pollution prevention plans . . . even though they were not on notice at the time.'' *Id.* at 68. Similarly, it would be unreasonable to penalize the State of Connecticut by rejecting its redesignation request for an area that is already attaining the 1997 and 2006 $PM_{2.5}$ standards and that met all applicable requirements known to be in effect at the time of the request. For EPA now to reject the redesignation request solely because the state did not expressly address subpart 4 requirements of which it had no notice, would inflict the same unfairness condemned by the Court in *Sierra Club* v. *Whitman.*

b. Subpart 4 Requirements and Connecticut's Redesignation Request

Even if EPA were to take the view that the Court's January 4, 2013 decision requires that, in the context of a pending redesignation for the 1997 and 2006 $PM_{2.5}$ standards, subpart 4 requirements were due and in effect at the time the State submitted its redesignation request, EPA proposes to determine that the Southwestern CT Area still qualifies for redesignation to attainment. As explained below, EPA believes that the redesignation request for the Southwestern CT Area, though not expressed in terms of subpart 4 requirements, substantively meets the requirements of that subpart for purposes of redesignating the area to attainment.

With respect to evaluating the relevant substantive requirements of subpart 4 for purposes of redesignating the Southwestern CT Area, EPA notes that subpart 4 incorporates components of subpart 1 of part D, which contains general air quality planning requirements for areas designated as nonattainment. *See* Section 172(c). Subpart 4 itself contains specific planning and scheduling requirements for PM_{10}[3] nonattainment areas, and under the Court's January 4, 2013 decision in *NRDC* v. *EPA,* these same statutory requirements also apply for $PM_{2.5}$ nonattainment areas. EPA has longstanding general guidance that interprets the 1990 amendments to the CAA, making recommendations to states for meeting the statutory requirements for SIPs for nonattainment areas. *See* ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clear Air Act Amendments of 1990,'' 57 FR 13498 (April 16, 1992) (the ''General Preamble''). In the General Preamble, EPA discussed the relationship of subpart 1 and subpart 4 SIP requirements, and pointed out that subpart 1 requirements were to an extent ''subsumed by, or integrally related to, the more specific PM–10 requirements.'' 57 FR 13538 (April 16, 1992). The subpart 1 requirements include, among other things, provisions for attainment demonstrations, reasonably available control measures (RACM), reasonable further progress

[2] *Sierra Club* v. *Whitman* was discussed and distinguished in a recent D.C. Circuit decision that addressed retroactivity in a quite different context, where, unlike the situation here, EPA sought to give its regulations retroactive effect. *National Petrochemical and Refiners Ass'n* v. *EPA.* 630 F.3d 145, 163 (D.C. Cir. 2010), rehearing denied 643 F.3d 958 (D.C. Cir. 2011), cert denied 132 S. Ct. 571 (2011).

[3] PM_{10} refers to particulates nominally 10 micrometers in diameter or smaller.

(RFP), emissions inventories, and contingency measures.

For the purposes of this redesignation, in order to identify any additional requirements which would apply under subpart 4, we are considering the Southwestern CT Area to be a ''moderate'' $PM_{2.5}$ nonattainment area. Under section 188 of the CAA, all areas designated nonattainment areas under subpart 4 would initially be classified by operation of law as ''moderate'' nonattainment areas, and would remain moderate nonattainment areas unless and until EPA reclassifies the area as a ''serious'' nonattainment area. Accordingly, EPA believes that it is appropriate to limit the evaluation of the potential impact of subpart 4 requirements to those that would be applicable to moderate nonattainment areas. Sections 189(a) and (c) of subpart 4 apply to moderate nonattainment areas and include the following: (1) An approved permit program for construction of new and modified major stationary sources (section 189(a)(1)(A)); (2) an attainment demonstration (section 189(a)(1)(B)); (3) provisions for RACM (section 189(a)(1)(C)); and (4) quantitative milestones demonstrating RFP toward attainment by the applicable attainment date (section 189(c)).

The permit requirements of subpart 4, as contained in section 189(a)(1)(A), refer to and apply the subpart 1 permit provisions requirements of sections 172 and 173 to PM_{10}, without adding to them. Consequently, EPA believes that section 189(a)(1)(A) does not itself impose for redesignation purposes any additional requirements for moderate areas beyond those contained in subpart 1.[4] In any event, in the context of redesignation, EPA has long relied on the interpretation that a fully approved nonattainment new source review program is not considered an applicable requirement for redesignation, provided the area can maintain the standard with a prevention of significant deterioration (PSD) program after redesignation. A detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, ''Part D New Source Review Requirements for Areas Requesting Redesignation to Attainment.'' *See also* rulemakings for Detroit, Michigan (60 FR 12467–12468, March 7, 1995); Cleveland-Akron-Lorain, Ohio (61 FR 20458, 20469–20470, May 7, 1996); Louisville, Kentucky (66 FR 53665, October 23, 2001); and Grand Rapids, Michigan (61 FR 31834–31837, June 21, 1996).

With respect to the specific attainment planning requirements under subpart 4,[5] when EPA evaluates a redesignation request under either subpart 1 and/or 4, any area that is attaining the $PM_{2.5}$ standard is viewed as having satisfied the attainment planning requirements for these subparts. For redesignations, EPA has for many years interpreted attainment-linked requirements as not applicable for areas attaining the standard. In the General Preamble, EPA stated that:

> The requirements for RFP will not apply in evaluating a request for redesignation to attainment since, at a minimum, the air quality data for the area must show that the area has already attained. Showing that the State will make RFP towards attainment will, therefore, have no meaning at that point.

''General Preamble for the Interpretation of Title I of the Clean Air Act Amendments of 1990''; (57 FR 13498, 13564, April 16, 1992).

The General Preamble also explained that

> [t]he section 172(c)(9) requirements are directed at ensuring RFP and attainment by the applicable date. These requirements no longer apply when an area has attained the standard and is eligible for redesignation. Furthermore, section 175A for maintenance plans * * * provides specific requirements for contingency measures that effectively supersede the requirements of section 172(c)(9) for these areas.

Id.

EPA similarly stated in its 1992 Calcagni memorandum that, ''The requirements for reasonable further progress and other measures needed for attainment will not apply for redesignations because they only have meaning for areas not attaining the standard.''

It is evident that even if we were to consider the Court's January 4, 2013 decision in *NRDC* v. *EPA* to mean that attainment-related requirements specific to subpart 4 should be imposed retroactively [6] and, thus, are now past due, those requirements do not apply to an area that is attaining the 1997 and 2006 $PM_{2.5}$ standards, for the purpose of evaluating a pending request to redesignate the area to attainment. EPA has consistently enunciated this interpretation of applicable requirements under section 107(d)(3)(E) since the General Preamble was published more than twenty years ago. Courts have recognized the scope of EPA's authority to interpret ''applicable requirements'' in the redesignation context. *See Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004).

Moreover, even outside the context of redesignations, EPA has viewed the obligations to submit attainment-related SIP planning requirements of subpart 4 as inapplicable for areas that EPA determines are attaining the standard. EPA's prior ''Clean Data Policy'' rulemakings for the PM_{10} NAAQS, also governed by the requirements of subpart 4, explain EPA's reasoning. They describe the effects of a determination of attainment on the attainment-related SIP planning requirements of subpart 4. *See* ''Determination of Attainment for Coso Junction Nonattainment Area,'' (75 FR 27944, May 19, 2010). *See also* Coso Junction proposed PM_{10} redesignation, (75 FR 36023, 36027, June 24, 2010); Proposed and Final Determinations of Attainment for San Joaquin Nonattainment Area (71 FR 40952, 40954–55, July 19, 2006; and 71 FR 63641, 63643–47 October 30, 2006). In short, EPA in this context has also long concluded that to require states to meet superfluous SIP planning requirements is not necessary and not required by the CAA, so long as those areas continue to attain the relevant NAAQS.

Elsewhere in this notice, EPA proposes to determine that the Southwestern CT Area has attained the 1997 and 2006 $PM_{2.5}$ standards. Under its longstanding interpretation, EPA is proposing to determine here that the area meets the attainment-related plan requirements of subparts 1 and 4.

Thus, EPA is proposing to conclude that the requirements to submit an attainment demonstration under 189(a)(1)(B), a RACM determination under section 172(c)(1) and section 189(a)(1)(c), a RFP demonstration under 189(c)(1), and contingency measure requirements under section 172(c)(9) are satisfied for purposes of evaluating the redesignation request.

c. Subpart 4 and Control of $PM_{2.5}$ Precursors

The D.C. Circuit in *NRDC* v. *EPA* remanded to EPA the two rules at issue in the case with instructions to EPA to re-promulgate them consistent with the requirements of subpart 4. EPA in this section addresses the Court's opinion with respect to $PM_{2.5}$ precursors. While past implementation of subpart 4 for PM_{10} has allowed for control of PM_{10} precursors such as NO_X from major stationary, mobile, and area sources in order to attain the standard as

[4] The potential effect of section 189(e) on section 189(a)(1)(A) for purposes of evaluating this redesignation is discussed below.

[5] I.e., attainment demonstration, RFP, RACM, milestone requirements, and contingency measures.

[6] As EPA has explained above, we do not believe that the Court's January 4, 2013 decision should be interpreted so as to impose these requirements on the states retroactively. *Sierra Club* v. *Whitman, supra.*

expeditiously as practicable, CAA section 189(e) specifically provides that control requirements for major stationary sources of direct PM_{10} shall also apply to PM_{10} precursors from those sources, except where EPA determines that major stationary sources of such precursors ''do not contribute significantly to PM_{10} levels which exceed the standard in the area.''

EPA's 1997 $PM_{2.5}$ implementation rule, remanded by the D.C. Circuit, contained rebuttable presumptions concerning certain $PM_{2.5}$ precursors applicable to attainment plans and control measures related to those plans. Specifically, in 40 CFR 51.1002, EPA provided, among other things, that a state was ''not required to address VOC [and ammonia] as . . . $PM_{2.5}$ attainment plan precursor[s] and to evaluate sources of VOC [and ammonia] emissions in the State for control measures.'' EPA intended these to be rebuttable presumptions. EPA established these presumptions at the time because of uncertainties regarding the emission inventories for these pollutants and the effectiveness of specific control measures in various regions of the country in reducing $PM_{2.5}$ concentrations. EPA also left open the possibility for such regulation of VOC and ammonia in specific areas where that was necessary.

The Court in its January 4, 2013 decision made reference to both section 189(e) and 40 CFR 51.1002, and stated that, ''In light of our disposition, we need not address the petitioners' challenge to the presumptions in [40 CFR 51.1002] that volatile organic compounds and ammonia are not $PM_{2.5}$ precursors, as subpart 4 expressly governs precursor presumptions.'' *NRDC* v. *EPA,* at 27, n.10.

Elsewhere in the Court's opinion, however, the Court observed:

> Ammonia is a precursor to fine particulate matter, making it a precursor to both $PM_{2.5}$ and PM_{10}. For a PM_{10} nonattainment area governed by subpart 4, a precursor is presumptively regulated. See 42 U.S.C. § 7513a(e) [section 189(e)].

Id. at 21, n.7. For a number of reasons, EPA believes that its proposed redesignation of the Southwestern CT Area is consistent with the Court's decision on this aspect of subpart 4. First, while the Court, citing section 189(e), stated that ''for a PM_{10} area governed by subpart 4, a precursor is 'presumptively regulated,' '' the Court expressly declined to decide the specific challenge to EPA's 1997 $PM_{2.5}$ implementation rule provisions regarding ammonia and VOC as precursors. The Court had no occasion to reach whether and how it was substantively necessary to regulate any specific precursor in a particular $PM_{2.5}$ nonattainment area, and did not address what might be necessary for purposes of acting upon a redesignation request.

However, even if EPA takes the view that the requirements of subpart 4 were deemed applicable at the time the state submitted the redesignation request, and disregards the implementation rule's rebuttable presumptions regarding ammonia and VOC as $PM_{2.5}$ precursors (and any similar provisions reflected in the guidance for the 2006 $PM_{2.5}$ standard), the regulatory consequence would be to consider the need for regulation of all precursors from any sources in the area to demonstrate attainment and to apply the section 189(e) provisions to major stationary sources of precursors. In the case of the Southwestern CT Area, EPA believes that doing so is consistent with proposing redesignation of the area for the 1997 and 2006 $PM_{2.5}$ standards. The Southwestern CT Area has attained the standard without any specific additional controls of VOC and ammonia emissions from any sources in the area.

Precursors in subpart 4 are specifically regulated under the provisions of section 189(e), which requires, with important exceptions, control requirements for major stationary sources of PM_{10} precursors.[7] Under subpart 1 and EPA's prior implementation rule, all major stationary sources of $PM_{2.5}$ precursors were subject to regulation, with the exception of ammonia and VOC. Thus, we must address here whether additional controls of ammonia and VOC from major stationary sources are required under section 189(e) of subpart 4 in order to redesignate the area for the 1997 $PM_{2.5}$ standard. As explained below, we do not believe that any additional controls of ammonia and VOC are required in the context of this redesignation.

In the General Preamble, EPA discusses its approach to implementing section 189(e). *See* 57 FR 13538–13542. With regard to precursor regulation under section 189(e), the General Preamble explicitly stated that control of VOCs under other Act requirements may suffice to relieve a state from the need to adopt precursor controls under section 189(e). 57 FR 13542. In this proposal, EPA proposes to determine that the SIP has met the provisions of section 189(e) with respect to ammonia and VOCs as precursors. This proposed determination is based on our findings that (1) the Southwestern CT Area contains no major stationary sources of ammonia, and (2) existing major stationary sources of VOC are adequately controlled under other provisions of the CAA regulating the ozone NAAQS.[8] In the alternative, EPA proposes to determine that, under the express exception provisions of section 189(e), and in the context of the redesignation of the area, which is attaining the 1997 and 2006 $PM_{2.5}$ standards, at present ammonia and VOC precursors from major stationary sources do not contribute significantly to levels exceeding the 1997 and 2006 $PM_{2.5}$ standards in the Southwestern CT Area.

EPA notes that its 1997 $PM_{2.5}$ implementation rule provisions in 40 CFR 51.1002 were not directed at evaluation of $PM_{2.5}$ precursors in the context of redesignation, but at SIP plans and control measures required to bring a nonattainment area into attainment of the 1997 $PM_{2.5}$ NAAQS. By contrast, redesignation to attainment primarily requires the area to have already attained due to permanent and enforceable emission reductions, and to demonstrate that controls in place can continue to maintain the standard. Thus, even if we regard the Court's January 4, 2013 decision as calling for ''presumptive regulation'' of ammonia and VOC for $PM_{2.5}$ under the attainment planning provisions of subpart 4, those provisions in and of themselves do not require additional controls of these precursors for an area that already qualifies for redesignation. Nor does EPA believe that requiring Connecticut to address precursors differently than they have already would result in a substantively different outcome.

Although, as EPA has emphasized, its consideration here of precursor requirements under subpart 4 is in the context of a redesignation to attainment, EPA's existing interpretation of subpart 4 requirements with respect to precursors in attainment plans for PM_{10} contemplates that states may develop attainment plans that regulate only those precursors that are necessary for purposes of attainment in the area in question, i.e., states may determine that only certain precursors need be regulated for attainment and control

[7] Under either subpart 1 or subpart 4, for purposes of demonstrating attainment as expeditiously as practicable, a state is required to evaluate all economically and technologically feasible control measures for direct PM emissions and precursor emissions, and adopt those measures that are deemed reasonably available.

[8] The Southwestern CT area has reduced VOC emissions through the implementation of various control programs including VOC Reasonably Available Control Technology regulations and various on-road and non-road motor vehicle control programs.

purposes.[9] Courts have upheld this approach to the requirements of subpart 4 for PM_{10}.[10] EPA believes that application of this approach to $PM_{2.5}$ precursors under subpart 4 is reasonable. Because the Southwestern CT Area has already attained the 1997 and 2006 $PM_{2.5}$ NAAQS with its current approach to regulation of $PM_{2.5}$ precursors, EPA believes that it is reasonable to conclude in the context of this redesignation that there is no need to revisit the attainment control strategy with respect to the treatment of precursors. Even if the Court's decision is construed to impose an obligation, in evaluating this redesignation request, to consider additional precursors under subpart 4, it would not affect EPA's approval here of Connecticut's request for redesignation of the Southwestern CT Area. In the context of a redesignation, the area has shown that it has attained the standard. Moreover, the state has shown and EPA is proposing to determine that attainment in this area is due to permanent and enforceable emissions reductions on all precursors necessary to provide for continued attainment. It follows logically that no further control of additional precursors is necessary. Accordingly, EPA does not view the January 4, 2013 decision of the Court as precluding redesignation of the Southwestern CT Area to attainment for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS at this time.

In sum, even if Connecticut were required to address precursors for the Southwestern CT Area under subpart 4 rather than under subpart 1, as interpreted in EPA's remanded $PM_{2.5}$ implementation rule, EPA would still conclude that the area had met all applicable requirements for purposes of redesignation in accordance with section 107(d)(3)(E)(ii) and (v).

d. Maintenance Plan and Evaluation of Precursors

With regard to the redesignation of Southwestern CT Area, in evaluating the effect of the Court's remand of EPA's implementation rule, which included presumptions against consideration of VOC and ammonia as $PM_{2.5}$ precursors, EPA in this proposal is also considering the impact of the decision on the maintenance plan required under sections 175A and 107(d)(3)(E)(iv). To begin with, EPA notes that the area has attained the 1997 annual and 2006 24-hour $PM_{2.5}$ standards and that the state has shown that attainment of those standards is due to permanent and enforceable emission reductions.

EPA proposes to determine that the State's maintenance plan shows continued maintenance of the standards by tracking the levels of the precursors whose control brought about attainment of the 1997 and 2006 $PM_{2.5}$ standards in the Southwestern CT Area. EPA, therefore, believes that the only additional consideration related to the maintenance plan requirements that results from the Court's January 4, 2013 decision is that of assessing the potential role of VOC and ammonia in demonstrating continued maintenance in this area. As explained below, based upon documentation provided by the State and supporting information, EPA believes that the maintenance plan for the Southwestern CT Area need not include any additional emission reductions of VOC or ammonia in order to provide for continued maintenance of the 1997 and 2006 $PM_{2.5}$ standards.

III. What are the criteria for redesignation to attainment?

The CAA sets forth the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA allows for redesignation provided that: (1) EPA determines that the area has attained the applicable NAAQS; (2) EPA has fully approved the applicable state implementation plan for the area under CAA section 110(k); (3) air-quality improvements are due to permanent and enforceable emission reductions; and (4) EPA has fully approved a maintenance plan for the area meeting the requirements of CAA section 175A; and (5) the state containing such area has met all requirements applicable to the area under CAA section 110 and part D.

EPA has provided guidance on redesignation in the General Preamble for the Implementation of Title I of the CAA Amendments of 1990 (April 16, 1992, 57 FR 13498) (supplemented on April 28, 1992, 57 FR 18070) and has provided further guidance on processing redesignation requests in the following documents:

1. ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (hereafter referred to as the ''Calcagni Memorandum'');

2. ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (CAA) Deadlines,'' Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992; and

3. ''Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment,'' Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, October 14, 1994.

IV. What is EPA's analysis of the State's request?

EPA is proposing to determine that the Southwestern CT Area has met all applicable redesignation criteria under CAA section 107(d)(3)(E). The basis for EPA's proposed approval of the redesignation request is discussed below.

A. Has the Southwestern CT Area attained the 1997 $PM_{2.5}$ NAAQS?

On November 15, 2010 (75 FR 69589), EPA determined that the New York Metropolitan Area, which includes the Southwestern CT Area, attained the 1997 annual $PM_{2.5}$ NAAQS. EPA determines that an area has attained the 1997 annual $PM_{2.5}$ NAAQS based on three complete, consecutive calendar years of quality-assured air quality data. To attain the annual standard, the three-year average of the annual mean $PM_{2.5}$ concentrations for designated monitoring sites in an area must not exceed 15.0 $\mu g/m^3$. The data must be collected and quality-assured in accordance with 40 CFR part 58, and recorded in EPA's Air Quality System (AQS). The monitors generally should have remained at the same location for the duration of the monitoring period required for demonstrating attainment.

Specifically, on November 15, 2010 (75 FR 69589), EPA determined that the New York Metropolitan Area attained the 1997 annual $PM_{2.5}$ NAAQS based on complete, quality-assured monitoring data for 2007–2009, and that it had attained this standard as of April 5, 2010, its applicable attainment date. Further discussion of pertinent air quality issues underlying this determination was provided in the notice of proposed rulemaking for EPA's determination of attainment for this Area, published on August 2, 2010 (75 FR 45076).

In addition, as discussed below with respect to the maintenance plan, the CT DEEP has committed to continue to operate an EPA-approved monitoring network in the area as necessary to demonstrate maintenance of the NAAQS. Connecticut remains obligated to continue to ensure the quality of monitoring data in accordance with 40 CFR part 58, and to enter all data into the AQS in accordance with Federal

[9] *See, e.g.,* ''Approval and Promulgation of Implementation Plans for California—San Joaquin Valley PM–10 Nonattainment Area; Serious Area Plan for Nonattainment of the 24-Hour and Annual PM–10 Standards,'' 69 FR 30006 (May 26, 2004) (approving a PM_{10} attainment plan that impose controls on direct PM_{10} and NO_X emissions and did not impose controls on SO_2, VOC, or ammonia emissions).

[10] *See, e.g., Assoc. of Irritated Residents* v. *EPA et al.,* 423 F.3d 989 (9th Cir. 2005).

guidelines. In summary, the area has attained the 1997 annual $PM_{2.5}$ NAAQS.

B. Has the Southwestern CT Area attained the 2006 $PM_{2.5}$ NAAQS?

On December 31, 2012 (77 FR 76867), EPA determined that the New York Metropolitan Area, which includes the Southwestern CT Area, attained the 2006 24-hour $PM_{2.5}$ NAAQS. EPA determines that an area has attained the 2006 24-hour $PM_{2.5}$ NAAQS based on three complete, consecutive calendar years of quality-assured air quality data. The 24-hour standard is met when the 98th percentile 24-hour concentration, as determined in accordance with 40 CFR part 50, Appendix N, is less than or equal to 35.0 μg/m^3. The data must be collected and quality-assured in accordance with 40 CFR part 58, and recorded in EPA's AQS. The monitors generally should have remained at the same location for the duration of the monitoring period required for demonstrating attainment.

Specifically, on December 31, 2012 (77 FR 76867), EPA determined that the New York Metropolitan Area attained the 2006 24-hour $PM_{2.5}$ NAAQS based on complete, quality-assured monitoring data for 2007–2009, 2008–2010, and 2009–2011, and that it had attained this standard ahead of December 14, 2014, its applicable attainment date. Further discussion of pertinent air quality issues underlying this determination was provided in the notice of proposed rulemaking for EPA's determination of attainment for this Area, published on August 30, 2012 (77 FR 52626).

In addition, as discussed below with respect to the maintenance plan, the CT DEEP has committed to continue to operate an EPA-approved monitoring network in the area as necessary to demonstrate maintenance of the NAAQS. Connecticut remains obligated to continue to ensure the quality of monitoring data in accordance with 40 CFR part 58, and to enter all data into the AQS in accordance with Federal guidelines. In summary, the area has attained the 2006 24-hour $PM_{2.5}$ NAAQS.

C. Has the State of Connecticut met all applicable requirements of Section 110 and Part D and does the Southwestern CT Area have a fully approved SIP under Section 110(k) of the CAA for purposes of redesignation to attainment?

EPA is proposing to determine that the Southwestern CT Area has met all SIP requirements applicable for purposes of this redesignation under section 110 of the CAA (General SIP Requirements) and that, upon final approval of the 2007 base-year emissions inventory, as discussed below in this proposed rulemaking, it will have met all applicable SIP requirements under part D of Title I of the CAA, in accordance with CAA section 107(d)(3)(E)(v). In addition, EPA is proposing to find that all applicable requirements of the Connecticut SIP for purposes of redesignation have been approved in accordance with CAA section 107(d)(3)(E)(ii). In making these proposed determinations, EPA ascertained which SIP requirements are applicable for purposes of redesignation of this Area, and concluded that the applicable portions of the SIP meeting these requirements are fully approved under section 110(k) of the CAA.

1. Section 110 and General SIP Requirements

Section 110(a)(2) of Title I of the CAA delineates the general requirements for a SIP, which include enforceable emissions limitations and other control measures, means, or techniques, provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality, and programs to enforce the limitations. The general SIP elements and requirements set forth in CAA section 110(a)(2) include, but are not limited to the following:

- Submittal of a SIP that has been adopted by the state after reasonable public notice and hearing;
- Provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality;
- Implementation of a source permit program; provisions for the implementation of Part C requirements (Prevention of Significant Deterioration (PSD));
- Provisions for the implementation of Part D requirements for New Source Review (NSR) permit programs;
- Provisions for air pollution modeling; and
- Provisions for public and local agency participation in planning and emission control rule development.

Section 110(a)(2)(D) of the CAA requires that SIPs contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. To implement this provision, EPA has required certain states to establish programs to address the interstate transport of air pollutants in accordance with the NO_X SIP Call, October 27, 1998 (63 FR 57356), amendments to the NO_X SIP Call, May 14, 1999 (64 FR 26298) and March 2, 2000 (65 FR 11222), and CAIR, May 12, 2005 (70 FR 25162). However, the CAA section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's designation and classification in that state. EPA believes that the requirements linked with a particular nonattainment area's designation and classifications are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state. Thus, EPA does not believe that these requirements are applicable requirements for purposes of redesignation.

Further, we conclude the other section 110 elements described above that are not connected with nonattainment plan submissions and not linked with an area's attainment status are also not applicable requirements for purposes of redesignation. A state remains subject to these requirements after an area is redesignated to attainment. We conclude that only the section 110 and part D requirements that are linked with a particular area's designation are the relevant measures which we may consider in evaluating a redesignation request. This approach is consistent with EPA's existing policy on applicability of conformity and oxygenated fuels requirements for redesignation purposes, as well as with section 184 ozone transport requirements. *See* Reading, Pennsylvania, proposed and final rulemakings (61 FR 53174, October 10, 1996), (62 FR 24826, May 7, 1997); Cleveland-Akron-Lorain, Ohio final rulemaking (61 FR 20458, May 7, 1996); and Tampa, Florida final rulemaking (60 FR 62748, December 7, 1995). *See also* the discussion on this issue in the Cincinnati, Ohio redesignation (65 FR at 37890, June 19, 2000) and in the Pittsburgh, Pennsylvania redesignation (66 FR at 53099, October 19, 2001).

We have reviewed Connecticut's SIP and have concluded that it meets the general SIP requirements under section 110 of the CAA, to the extent they are applicable for purposes of redesignation. EPA has previously approved provisions of the Connecticut SIP addressing section 110 requirements (including provisions addressing particulate matter). On September 4, 2008 and September 18, 2009, Connecticut made submittals for the 1997 annual and 2006 24-hour $PM_{2.5}$ standards, respectively, addressing ''infrastructure SIP'' elements required by section 110(a)(2) of the CAA. EPA approved or conditionally approved all elements of Connecticut's submittals on October 16, 2012, at 77 FR 63228. The

requirements of section 110(a)(2), however, are statewide requirements that are not linked to the $PM_{2.5}$ nonattainment status of the Southwestern CT Area. Therefore, EPA believes that these SIP elements are not applicable requirements for purposes of review of the State's $PM_{2.5}$ redesignation request.

EPA also has previously approved $PM_{2.5}$ and $PM_{2.5}$ precursor control measures that are permanent and enforceable controls that will remain in place following redesignation (see Table 1).

TABLE 1—LIST OF CONNECTICUT CONTROL MEASURES FOR $PM_{2.5}$ AND $PM_{2.5}$ PRECURSORS

Name of control measure	Type of measure	Approval citation
Tier 2 Vehicle Standards and Gasoline Sulfur Standards	federal rule	Promulgated at 40 CFR part 86.
Heavy-Duty Diesel and Gasoline Highway Vehicle Standards.	federal rule	Promulgated at 40 CFR part 86.
Motorcycle Exhaust Standards	federal rule	Promulgated at 40 CFR part 86.
Large Non-road Diesel Engine Standards	federal rule	Promulgated at 40 CFR part 89.
Non-road Spark-Ignition Engines and Recreational Engine Standards.	federal rule	Promulgated at 40 CFR part 90.
NO_X SIP Call	federal rule	63 FR 57356 (10/27/1998).
CAIR	federal rule	70 FR 25162 (5/12/2005).
Control of Sulfur Compound Emissions 19–508–19	SIP-approved state regulation.	46 FR 56612 (11/18/1981).
Control of SO_2 emissions from power plants and other large stationary sources 22a–174–19a.	SIP-approved state regulation.	Approval signed 4/26/2013, not yet published. See CT Regional Haze SIP docket (EPA–R01–OAR–2009–0919).
Control of NO_X Emissions 22a–174–22	SIP-approved state regulation.	62 FR 52016 (10/06/1997).
Post-2002 NO_X Budget Program 22a–174–22b	SIP-approved state regulation.	65 FR 81743 (12/27/2000); superseded by CAIR (22a–174–22c).
CAIR NO_X Ozone Season Trading Program 22a–174–22c.	SIP-approved state regulation.	73 FR 4105 (01/24/2008).
Control of Particulate Emissions 19–508–18	SIP-approved state regulation.	47 FR 41958 (09/23/1982).
Emission Standards and On-Board Diagnostic II Test Requirements for Periodic Motor Vehicle Inspection and Maintenance 22a–174–27.	SIP-approved state regulation.	73 FR 74019 (12/05/2008).
Low Emission Vehicles 22a–174–36b	SIP-approved state regulation.	64 FR 44411 (08/16/1999).
Municipal Waste Combustors 22a–174–38	SIP-approved state regulation.	66 FR 63311 (12/06/2001).
Permit to Construct and Operate Stationary Sources 22a–174–3a.	SIP-approved state regulation.	76 FR 26933 (05/10/2011).

2. Part D SIP Requirements

EPA has determined that, upon approval of the base-year emissions inventories discussed below, the Connecticut SIP will meet the applicable SIP requirements for the Southwestern CT Area applicable for purposes of redesignation under part D of the CAA. Subpart 1 of part D, found in sections 172–176 of the CAA, sets forth the basic nonattainment requirements applicable to all nonattainment areas.

Subpart 1 Section 172 Requirements

On November 15, 2010 (75 FR 69589) and December 31, 2012 (77 FR 76867), EPA made determinations that the New York Metropolitan Area, including the Southwestern CT Area, is attaining the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, respectively. These determinations of attainment were based on quality-assured and certified air-quality data for the 2007–2009 monitoring period (1997 NAAQS) and for the 2007–2009, 2008–2010, and 2009–2011 monitoring periods (2006 NAAQS) showing that the Southwestern CT Area had attained the applicable NAAQS. Monitoring data for 2012 are also consistent with continued attainment of the standards. Under EPA's Clean Data Policy and pursuant to 40 CFR 51.1004(c), upon determination by EPA that an area designated nonattainment of the $PM_{2.5}$ NAAQS has attained the standard, the requirement for such an area to submit an attainment demonstration and associated reasonably achievable control technology (RACT)/RACM, RFP, contingency measures, and other planning SIPs related to the attainment of the $PM_{2.5}$ NAAQS are suspended until EPA determines that the area has again violated the $PM_{2.5}$ NAAQS, at which time such plans are required to be submitted.[11] As a result of the determinations of attainment for the Southwestern CT Area, the only remaining requirement under CAA section 172 to be considered is the emissions inventory required under CAA section 172(c)(3).

In this rulemaking action, EPA is proposing to approve Connecticut's 2007 base-year emissions inventory in accordance with section 172(c)(3) of the CAA. Final approval of the 2007 base-year emissions inventory will satisfy the emissions inventory requirement under section 172(c)(3) of the CAA.

The General Preamble for Implementation of Title I also discusses the evaluation of these requirements in the context of EPA's consideration of a redesignation request. The General Preamble sets forth EPA's view of applicable requirements for purposes of evaluating redesignation requests when an area is attaining the standard. *See*

[11] Nevertheless, CT DEEP did submit a SIP on November 18, 2008, which included an attainment demonstration for the 1997 annual $PM_{2.5}$ standard for the Southwestern CT Area. In its June 22, 2012 redesignation request, CT DEEP states that it will withdraw the attainment demonstration SIP, effective one day after EPA signs the final rule approving Connecticut's redesignation request and maintenance plans.

General Preamble for Implementation of Title I (57 FR 13498, April 16, 1992).

Because attainment of the 1997 annual and 2006 24-hour $PM_{2.5}$ standards has been reached for the Southwestern CT Area, no additional measures are needed to provide for attainment, and CAA section 172(c)(1) requirements for an attainment demonstration and RACT/RACM are no longer considered to be applicable for purposes of redesignation as long as the area continues to attain the standards until redesignation. *See* 40 CFR 51.1004(c). The RFP requirement under CAA section 172(c)(2) and contingency measures requirement under CAA section 172(c)(9) are similarly not relevant for purposes of redesignation.

Section 172(c)(3) of the CAA requires submission and approval of a comprehensive, accurate and current inventory of actual emissions. The maintenance plan submitted by CT DEEP includes a 2007 base-year emissions inventory that meets this requirement. The 2007 base-year emissions inventory for the Southwestern CT Area, compiled jointly by CT DEEP and the Mid-Atlantic Regional Air Management Association (MARAMA), contains $PM_{2.5}$ (including condensables), and $PM_{2.5}$ precursors, SO_2 and NO_X. MARAMA emissions inventories also include the $PM_{2.5}$ precursors ammonia (NH_3) and volatile organic compounds (VOC). *See* Appendix C of Connecticut's June 22, 2012 redesignation request. The emissions inventories cover the general source categories of EGU point sources, non-EGU point sources (i.e., individual industrial, commercial, and institutional facilities), area sources (i.e., aggregated small, non-permitted sources such as small industrial/commercial facilities, residential heating furnaces, and road dust re-entrainment), on-road mobile sources (i.e., cars, trucks, buses, and other vehicles on public roadways), and nonroad mobile sources (e.g., marine vessels, airplanes, railroad locomotives, forklifts, lawn and garden equipment, portable generators (non-road MAR). However, there is one exception to the source category coverage mentioned above. MARAMA's VOC and NH_3 emission estimates did not include estimates for the on-road mobile sector, and so the emission values in Table 4 below represent values taken from EPA's regulatory impact analysis for the PM NAAQS.

A summary of the inventory development process is given below under ''EPA's analysis of the Southwestern CT Area maintenance plan.'' Connecticut provided detailed descriptions of the derivation of emission estimates in Appendices A–I of their June 22, 2012 submittal.

Tables 2 and 3 show the 2007 base-year emissions for $PM_{2.5}$ and $PM_{2.5}$ precursors, SO_2 and NO_X, which are the principal $PM_{2.5}$ precursors in the Southwestern CT Area. Table 4 shows the other $PM_{2.5}$ precursors, ammonia and VOC, for the entire state of Connecticut. VOC emission levels in Connecticut, including the Southwestern CT Area, have historically been well-controlled under SIP requirements related to ozone and other pollutants. Total ammonia emissions throughout the state are very low, estimated for 2007 to be 5,765 tons per year. This amount of statewide ammonia emissions is small compared to the total amounts of SO_2 and NO_X, and even direct $PM_{2.5}$ emissions from sources within just the two-county Southwestern CT Area. Moreover, available information shows that no precursor, including VOC and ammonia, is expected to increase over the maintenance period so as to interfere with or undermine the State's maintenance demonstration, as further discussed below under ''EPA's analysis of the Southwestern CT Area maintenance plan.'' The proposed approval of the 2007 base-year emissions inventory in this rulemaking action will, when finalized, meet the requirements of CAA section 172(c)(3).

TABLE 2—NEW HAVEN COUNTY, CT: $PM_{2.5}$, SO_2 AND NO_X EMISSIONS (TPY) FOR BASE-YEAR 2007 BY SOURCE SECTOR

Sector	SO_2	NO_X	$PM_{2.5}$
Point (EGU)	822.7	639.6	88.1
Point (Non-EGU)	55.6	822.7	40.4
Area	3,707.7	2,936.1	1,900.3
Marine Vessels, Airplanes, RR Locomotives (MAR)	727.4	3,945.9	168.5
Nonroad (NMIM)	174.1	3,688.1	279.1
Onroad (MOVES)	91.8	11,502.7	389.6
Total	5,579.2	23,535.1	2,866.0

Note: Primary $PM_{2.5}$ includes filterables and condensables.

TABLE 3—FAIRFIELD COUNTY, CT: $PM_{2.5}$, SO_2 AND NO_X EMISSIONS (TPY) FOR BASE-YEAR 2007 BY SOURCE SECTOR

Sector	SO_2	NO_X	$PM_{2.5}$
Point (EGU)	3,311.2	2,268.5	283.5
Point (Non-EGU)	154.8	1,875.4	44.7
Area	3,917.3	3,088.8	1,991.5
Marine Vessels, Airplanes, RR Locomotives (MAR)	353.4	3,034.2	119.9
Nonroad (NMIM)	215.8	4,648.1	403.0
Onroad (MOVES)	84.3	11,888.9	404.4
Total	8,036.7	26,804.0	3,247.0

TABLE 4—CONNECTICUT: AMMONIA AND VOC EMISSIONS (TPY) FOR BASE-YEAR 2007 BY SOURCE SECTOR.

Sector	VOC	Ammonia (NH_3)
Point (EGU)	143	0
Point (nonEGU)	1,447	0
Area	57,253	4,421
Non-road mobile	20,721	16
Commercial Marine Vessels	161	3
Airports	509	0
Railroad Locomotives	73	1
On-road mobile	28,967	1,324
Total	109,274	5,765

Section 172(c)(4) of the CAA requires the identification and quantification of allowable emissions for major new and modified stationary sources in an area, and CAA section 172(c)(5) requires new source permits for the construction and operation of new and modified major stationary sources anywhere in the nonattainment area. EPA has determined that, since the PSD requirements will apply after redesignation, areas being redesignated need not comply with the requirement that a nonattainment NSR program be approved prior to redesignation, provided that the area demonstrates maintenance of the NAAQS without part D NSR. A more detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994 entitled, ''Part D New Source Review Requirements for Areas Requesting Redesignation to Attainment.'' Nevertheless, Connecticut currently has an approved NSR program, established in RCSA section 22a–174–2a with amendments in 22a–174–3a. *See* 68 FR 9009 (February 27, 2003) and 76 FR 26933 (May 10, 2011). However, Connecticut's PSD program for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS will become effective in Southwestern CT Area (i.e., New Haven and Fairfield Counties) upon redesignation to attainment.

Section 172(c)(6) of the CAA requires the SIP to contain control measures necessary to provide for attainment of the NAAQS. Because attainment has been reached for the Southwestern CT Area, no additional measures are needed to provide for attainment.

Section 172(c)(7) of the CAA requires the SIP to meet the applicable provisions of CAA section 110(a)(2). As noted previously, we believe the Connecticut SIP meets the requirements of CAA section 110(a)(2) that are applicable for purposes of redesignation.

Subpart 1, Section 176 Conformity Requirements

Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that federally-supported or funded activities, including highway projects, conform to the air quality planning goals in the applicable SIPs. The requirement to determine conformity applies to transportation plans, programs, and projects developed, funded or approved under title 23 of the U.S. Code and the Federal Transit Act (transportation conformity) as well as to all other federally-supported or funded projects (general conformity). State conformity revisions must be consistent with federal conformity regulations relating to consultation, enforcement and enforceability, which EPA promulgated pursuant to CAA requirements.

EPA interprets the conformity SIP requirements as not applying for purposes of evaluating the redesignation request under section 107(d) for two reasons. First, the requirement to submit SIP revisions to comply with the conformity provisions of the CAA continues to apply to areas after redesignation to attainment, since such areas would be subject to a section 175A maintenance plan. Second, EPA's federal conformity rules require the performance of conformity analyses in the absence of federally-approved state rules. Therefore, because areas are subject to the conformity requirements regardless of whether they are redesignated to attainment and, because they must implement conformity under federal rules if state rules are not yet approved, it is reasonable to view these requirements as not applying for purposes of evaluating a redesignation request. See *Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001), upholding this interpretation. *See* also 60 FR 62748, 62749–62750 (December 7, 1995) (Tampa, Florida).

Connecticut's June 22, 2012 redesignation request included new fine particle motor vehicle emissions budgets (MVEBs) as part of their maintenance plan. The SIP establishes annual direct $PM_{2.5}$ and annual NO_X transportation conformity budgets for 2017 and 2025 to ensure that future emissions from on-road mobile sources provide for continuing attainment of the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. Connecticut submitted on-road MVEBs for the Southwestern CT Area of 575.8 tpy direct $PM_{2.5}$ and 12,791.8 tpy NO_X for 2017, and 516 tpy direct $PM_{2.5}$ and 9,728.1 tpy NO_X for 2025.

EPA New England sent a letter to CT DEEP on January 8, 2013, stating that the 2017 and 2025 MOVES2010 MVEBs in the June 22, 2012 SIP submittal are adequate for transportation conformity purposes. On February 5, 2013, (78 FR 8122) EPA notified the public through a **Federal Register** notice of adequacy that EPA has found that the 2017 and 2025 MVEBs adequate for transportation conformity purposes. These MVEBs became effective on February 20, 2013. For the Southwestern CT Area, Connecticut must use the MVEBs in any future conformity determination on or after the effective date of the notice of adequacy. MVEBs are discussed further in section V.

3. Does the Southwestern CT Area have a fully approved applicable SIP under Section 110(k) of the CAA?

Upon final approval of the 2007 base-year emissions inventory, EPA will have fully approved the Connecticut portion of the New York–N. New Jersey–Long Island, NY–NJ–CT Area under section 110(k) of the CAA for all requirements applicable for purposes of redesignation to attainment for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. As noted above, in this rulemaking action, EPA is proposing to approve the Southwestern CT Area's 2007 base-year emissions inventory (submitted as part of its maintenance plan) as meeting the requirement of section 172(c)(3) of the CAA for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. Therefore, upon final approval of the 2007 base-year emissions inventory, Connecticut will have satisfied all applicable requirements under part D of Title I of the CAA for the Southwestern CT Area.

D. Are the air quality improvements in the Southwestern CT Area due to permanent and enforceable reductions in emissions?

EPA proposes to find that the state has demonstrated that the observed air quality improvement in the Southwestern CT Area is due to permanent and enforceable reductions in emissions resulting from implementation of the SIP, federal measures, and other state-adopted measures, listed in Table 1 above. As shown in the state's submittal and supported by EPA rulemaking (see 75 FR 69589, November 15, 2010 and 77 FR 76867, December 31, 2012), the Area came into attainment with the 1997 annual $PM_{2.5}$ standard based on $PM_{2.5}$ data for 2007–2009, and into attainment with the 2006 24-hour standard based on $PM_{2.5}$ data for the 2007–2009, 2008–2010, and 2009–2011 monitoring periods. The Area has remained in

attainment and the air quality has improved in the area. Attainment is the direct result of permanent and enforceable emission reductions and not favorable meteorology or economic downturn.

Connecticut's redesignation request documents substantial emission reductions in $PM_{2.5}$ and $PM_{2.5}$ precursors both in upwind states and within Connecticut. For example, the state's request notes that due to federal programs including EPA's acid rain program, Ozone Transport Commission's NO_X budget program, and EPA's NO_X SIP Call, emissions from EGUs from states impacting Connecticut declined by 66 percent for NO_X and by 48 percent for SO_2 between 2002 and 2009.

1. Federal Measures Implemented

Reductions in $PM_{2.5}$ and $PM_{2.5}$ precursor emissions (e.g., NO_X and SO_2) have occurred statewide and in upwind states as a result of federal measures with additional emission reductions expected to occur in the future. The maintenance plan for the Southwestern CT Area lists post-2002 federal measures (as well as state measures) that have reduced $PM_{2.5}$ and $PM_{2.5}$ precursor emissions from stationary and mobile sources. These measures include the following:

(a) Tier 2 Emission Standards for Vehicles and Gasoline Sulfur Standards

These emission control requirements, which were published on February 10, 2000 (65 FR 6698), result in lower NO_X, and SO_2 emissions from new cars and light duty trucks, including sport utility vehicles. The Federal rules were phased in between 2004 and 2009. EPA has estimated that, after phasing in the new requirements, new vehicles emit less NO_X in the following percentages: Passenger cars (light duty vehicles)—77 percent; light duty trucks, minivans, and sports utility vehicles—86 percent; and larger sports utility vehicles, vans, and heavier trucks—69–95 percent. EPA expects fleet-wide average emissions to decline by similar percentages as new vehicles replace older vehicles. The Tier 2 standards also reduced the sulfur content of gasoline to 30 parts per million (ppm) beginning in January 2006, which reflects up to a 90 percent reduction in sulfur content.

(b) Heavy-Duty Diesel Rule and Gasoline Highway Vehicle Standards

EPA published the heavy-duty diesel rule on January 18, 2001 (66 FR 5002). This rule, designed to reduce NO_X and VOC emissions from heavy-duty diesel and from gasoline highway vehicles, took effect in 2004 and 2005, respectively. A second phase, which took effect in 2007, reduced $PM_{2.5}$ emissions from heavy-duty highway engines and further reduced the highway diesel fuel sulfur content to 15 ppm. The program is estimated to achieve a 90-percent reduction in direct $PM_{2.5}$ emissions and a 95-percent reduction in NO_X emissions for these new engines using low-sulfur diesel fuel when compared to engines using higher sulfur diesel. The reduction in fuel sulfur content also yielded an immediate reduction in particulate sulfate emissions from all diesel vehicles.

(c) Motorcycle Exhaust Standards

In 2004, EPA published a final rule to implement improved exhaust emission standards on new highway motorcycles (69 FR 2398). These standards apply to model-year 1978 and newer gasoline-fuels motorcycles, and to later model-year motorcycles that use other fuel types (1990 model year for methanol; 1997 model year for natural gas or liquefied petroleum gas). For 2006 and later model-year new motorcycles, the standards apply regardless of fuel. Starting with the 2006 model year, EPA re-defined Class I to include motorcycles with engines smaller than 50 cubic centimeters. In addition, motorcycles with the largest engines are subject to more stringent NO_X and hydrocarbon standards beginning with the 2010 model year.

(d) Non-Road Diesel Rule

In June 2004, EPA published a new rule for large nonroad diesel engines, such as those used in construction, agriculture, and mining, to be phased in from 2008 to 2014 (69 FR 38958). The rule also reduced the sulfur content in nonroad diesel fuel by over 99 percent. Prior to 2006, nonroad diesel fuel averaged approximately 3,400 ppm sulfur. This rule limited nonroad diesel sulfur content to 500 ppm by 2006, with a further reduction to 15 ppm by 2010. Because of the timing of the new requirements, most reductions will occur during the maintenance period for the Southwestern CT Area as the fleet of older non-road diesel engines is gradually replaced with newer, lower-emitting engines. However, the required reduction in fuel sulfur content yielded an immediate reduction in sulfate particle emissions from all non-road diesel vehicles.

(e) Non-Road Spark-Ignition Engines and Recreational Engine Standards

On November 8, 2002, EPA promulgated emission standards for groups of previously unregulated non-road engines (67 FR 68242). These emission standards for several groups of nonroad engines, including large spark-ignition engines, such as those used in forklifts and airport ground-service equipment; recreational vehicles using spark-ignition engines, such as off-highway motorcycles, all-terrain vehicles, and snowmobiles; and recreational marine diesel engines. Emission standards from large spark-ignition engines were implemented in two tiers, with Tier 1 starting in 2004 and Tier 2 in 2007. Recreational-vehicle emission standards were phased in from 2006 through 2012. Marine diesel engine standards were phased in from 2006 through 2009. With full implementation of the entire non-road spark-ignition engine and recreational engine standards, an 80 percent reduction in NO_X is expected by 2020, as affected fleets are gradually replaced.

(f) NO_X SIP Call

In October 1998, EPA issued the NO_X SIP Call pursuant to the CAA. This required 22 states (including Connecticut) and the District of Columbia to reduce NO_X emissions from EGUs (i.e., power plants) and non-EGUs, such as industrial boilers, internal combustion engines, and cement kilns. (63 FR 57356, October 27, 1998). The program was intended to reduce emissions in states determined to be significantly contributing to violations of the 1-hour ozone NAAQS in downwind states. Affected states were required to comply with Phase I of the SIP Call beginning in 2003/2004 and with Phase II beginning in 2007. EPA approved Connecticut's NO_X SIP Call rule (NO_X Budget Program) on September 28, 1999 (64 FR 52233). This program was incorporated into Connecticut's CAIR program (see below) in September 2007. Emission reductions resulting from regulations developed in response to the NO_X SIP Call are permanent and enforceable.

(g) CAIR and CSAPR

EPA approved Connecticut's CAIR rules in 2007 (73 FR 4105, September 4, 2007) as a control measure for reducing NO_X emissions from EGUs. As previously discussed, the Court's 2008 remand of CAIR left the rule in place to ''temporarily preserve the environmental values covered by CAIR'' until EPA replaced it with a rule consistent with the Court's opinion, and the Court's August 2012 decision on CSAPR also left CAIR in effect until the legal challenges to CSAPR are resolved. As noted, EPA believes it is appropriate to allow states to rely on CAIR, and the

existing emissions reductions achieved by CAIR, as sufficiently permanent and enforceable pending a valid replacement rule, for purposes such as redesignation.

Furthermore, as previously discussed, the air quality modeling analysis conducted for CSAPR demonstrates that the Southwestern CT Area would be able to attain the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS even in the absence of either CAIR or CSAPR. EPA's modeling projections show that all ambient monitors in the Southwestern CT Area are expected to continue to maintain compliance in the 2012 and 2014 ''no CAIR'' base cases. Therefore, none of the ambient monitoring sites in the Southwestern CT Area are ''receptors'' that EPA projects will have future nonattainment problems or difficulty maintaining the NAAQS.

2. SIP-Approved State Measures

In addition to the federal control measures described above, Connecticut is implementing several state programs that have contributed to significant reductions in ambient levels of direct $PM_{2.5}$ and $PM_{2.5}$ precursors. These are listed on Table 1 and include, for example, regulations to reduce emissions of SO_2 and NOx from major stationary sources, including power plants; low-sulfur fuel requirements; addition of a non-ozone season NOx limit to all sources subject to the NO_X Budget Program; the addition of PM standards to certain fuel-burning equipment and stationary reciprocating internal-combustion engines; updates to the state's motor-vehicle emissions testing and Inspection and Maintenance (I/M) programs; adoption of Low Emission Vehicle (LEV) standards; and limits on NOx emissions from Municipal Waste Combustors. As noted in Table 1, all of the regulations have been approved by EPA into the CT SIP.

Based on the information summarized above, Connecticut has adequately demonstrated that the improvement in air quality is due to permanent and enforceable emissions reductions. EPA concludes that significant reductions result from federal requirements and regulation of precursors under the NOx SIP Call and CAIR, which are expected to continue into the future.

E. Does the Southwestern CT Area have a fully approved maintenance plan pursuant to Section 175a of the CAA?

In conjunction with its request to redesignate the Southwestern CT Area to attainment status, Connecticut submitted a SIP revision to provide for the maintenance of the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS in the Southwestern CT Area until 2025.

1. Maintenance Plan Requirements

Section 175 of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under CAA section 175A, the plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after EPA approves an area's redesignation. Eight years after the redesignation, Connecticut must submit a revised maintenance plan demonstrating that attainment will continue to be maintained for the 10 years following the initial 10-year period. To address the possibility of future NAAQS violations, the maintenance plan must contain contingency measures, with a schedule for implementation, as EPA deems necessary, to assure prompt correction of any violations of the 1997 annual or 2006 24-hour $PM_{2.5}$ NAAQS that occur after redesignation of the Area to attainment. The Calcagni Memorandum dated September 4, 1992, provides additional guidance on the content of a maintenance plan. This memorandum states that a $PM_{2.5}$ maintenance plan should include the following: (1) An emissions inventory sufficient to ensure attainment; (2) a demonstration that the plan ensures maintenance of the NAAQS for 10 years following approval of the redesignation request; (3) a commitment to maintain an appropriate monitoring network; (4) a method to verify continued attainment; and (5) a contingency plan to be implemented if NAAQS violations occur during the maintenance period.

2. EPA's Analysis of the Southwestern CT Area Maintenance Plan

a. Attainment Emissions Inventory

An attainment emissions inventory is a comprehensive inventory of the actual emissions from sources within a nonattainment area for a time period used to show that the area has come into attainment with the NAAQS. Inventories used for Connecticut's $PM_{2.5}$ redesignation request were developed as an extension to regional efforts in the Mid-Atlantic/Northeast Visibility Union (MANE–VU) area to create inventories for use in photochemical modeling for the 2008 ozone NAAQS and Regional Haze SIPs. For $PM_{2.5}$ redesignation efforts, MARAMA took the lead in coordinating with several states (including Connecticut) to develop an inventory for 2025 to supplement those already under development (2007, 2017 and 2020 inventories), as well as to modify the 2007 inventory for $PM_{2.5}$ redesignation. A summary of the inventory development process is given below. For more information about how the inventories were developed, as well as quality-assurance procedures, see Appendices in Connecticut's $PM_{2.5}$ Redesignation Request at *http://www.regulations.gov:* Docket number EPA–R01–OAR–2013–0020.

In the Southwestern CT Area, compliance with the 1997 annual $PM_{2.5}$ NAAQS was achieved in 2001 and compliance with the 24-hour NAAQS was achieved in 2008. Therefore, Connecticut chose 2007 as the initial year for the attainment inventory. The end of the maintenance period was established as 2025, with an interim year of 2017, which is consistent with the CAA section 175A(a) requirement that the maintenance plan provide for maintenance of the NAAQS for at least 10 years after EPA approval of the redesignation request.

Emission estimates were developed for EGU point sources, non-EGU point sources, area sources, non-road mobile sources, and on-road mobile sources. The MANE–VU $PM_{2.5}$ redesignation inventories were prepared only for the area classified as nonattainment for the annual and 24-hour $PM_{2.5}$ NAAQS (i.e., in Connecticut, Fairfield County and New Haven Counties). The inventories were developed at the county level for the area-source and mobile-source categories and at the process level for point-source categories, then summed to the county level. EPA concurs with Connecticut that the use of annual inventories was also appropriate for demonstrating continued compliance with the 24-hour $PM_{2.5}$ NAAQS during the maintenance period as analysis of monitoring data for the Southwestern CT Area showed that elevated 24-hour $PM_{2.5}$ levels occur in multiple seasons (primarily summer and winter).

Point source emissions—For the 2007 point-source inventory, CT DEEP provided MARAMA with actual 2007 emissions for all EGU and non-EGU point sources. EGU sources were considered to be only those sources that report hourly emissions to EPA's Clean Air Markets Division (CAMD) database. All other point sources (including non-EGUs in CAMD, small non-CAMD EGUs and all other non-EGUs) were grouped as non-EGU point sources. The 2007 inventory also included banked continuous emission reduction credits (CERCs) for potential use as offsets in new source review permits. MARAMA calculated components of PM emissions (i.e., PM-primary, PM-filterable, and PM-condensable) that were missing from the point-source inventory provided by Connecticut. For EGUs, MARAMA used updated condensable emission factors; for non-EGUs,

MARAMA used a similar process to that used in developing the 2002 MANE–VU Version 3 inventory. For information on $PM_{2.5}$ augmentation processes, see Appendix A of Connecticut's $PM_{2.5}$ Redesignation Request at *http://www.regulations.gov:* Docket number EPA–R01–OAR–2013–0020.

To estimate EGU emissions for future years, MARAMA extrapolated the 2007 EGU emissions based on Annual Energy Outlook (AEO) electricity generation projections. The appropriate AEO 2011 growth factor was applied to the 2007 emissions to calculate a ''growth only'' emission value for 2017 and 2025.

MARAMA developed non-EGU point-source growth factors for Connecticut using employment or fuel consumption projections, depending on the source category. MARAMA extrapolated 2006–2016 employment forecasts from the Connecticut Department of Labor through 2025 to develop emission estimates for non-fuel burning sources such as manufacturing operations. AEO fuel-use projections published in 2010 by the U.S. Energy Information Administration were used to develop growth factors for fuel-consuming sources.

MARAMA examined adopted federal and regional control strategies to determine those that would result in post-2007 emission reductions of $PM_{2.5}$ or $PM_{2.5}$ precursors from non-EGU point sources. They determined that the maximum achievable control technology (MACT) standards for reciprocating internal combustion engines (RICE) and for industrial/commercial/institutional (ICI) boilers and process heaters will provide NO_X or $PM_{2.5}$ emission reductions from several non-EGU source categories during the maintenance period.

Area source emissions—CT DEEP initially instructed MARAMA to use EPA's 2008 National Emissions Inventory (NEI) emission values for all area-source categories for the attainment year inventory. However, during the quality-assurance effort, a number of categories were discovered to be either missing from the 2008 NEI or to have used incorrect emission-factor assumptions for Connecticut. Therefore, substitutions were made from the 2005 NEI or from CT DEEP's draft 2005 periodic emission inventory (PEI). For residential wood combustion (RWC), MARAMA's contractor used EPA's RWC tool with updated 2007 data to produce emission estimates.

MARAMA applied growth factors to the 2007 MANE–VU area-source inventory to account for anticipated changes in fuel use, population and economic activity during the maintenance period. For Connecticut, growth factors were developed using the following sets of data: (1) AEO New England region fuel consumption forecasts; (2) county-level population projections; (3) state-level employment projections; (4) county-level vehicle miles traveled (VMT) projections; and (5) EPA projections for RWC.

On-road mobile sources—EPA's MOVES2010 (MOtor Vehicle Emission Simulator) is now the official model for estimating air-pollution emissions from on-road mobile sources including buses, cars, trucks and motorcycles for SIP purposes. This model replaces MOBILE6.2, EPA's previous mobile source model. To assist in the transition to the new model, EPA developed software tools to convert certain MOBILE6.2 inputs for MOVES.

CT DEEP assembled updated MOVES data sets and performed MOVES runs with updated data for 2009, 2017 and 2025. Instead of developing updated 2007 emission estimates, Connecticut used 2009 MOVES on-road emission estimates in the $PM_{2.5}$ attainment year inventory because (1) EPA had previously approved 2009 transportation conformity MVEBs for Connecticut that were determined using MOBILE6.2, and (2) the use of the lower 2009 on-road emission estimates for 2007 ensured that the total attainment year inventory across all source sectors will be more conservative (i.e., lower) than if 2007 on-road emissions were used. Since emissions through the end of the maintenance period must be no higher than the attainment-year inventory, this approach provides additional assurance that NAAQS compliance will continue through the maintenance period.

Nonroad mobile emissions—Non-road sources include internal combustion engines used to propel marine vessels, airplanes, and locomotives, or to operate equipment such as forklifts, lawn and garden equipment, portable generators, etc. For activities other than marine vessels, airplanes, and railroad locomotives (MAR), the inventory was developed using the most current version of EPA's NONROAD model as embedded in the National Mobile Inventory Model (NMIM). Because the NONROAD model does not include emissions from MAR sources, these emissions were estimated based on data and methodologies used in recent EPA regulatory impact analyses.

The emission inventories for Connecticut show that between 2002 (one of the years for which the Area's nonattainment designation was based) and 2009, an attainment year, in-state emissions were reduced by 679 tons per year (4%) for direct $PM_{2.5}$, 36,166 tons per year (30%) for NO_X, and 9,233 tons per year (29%) for SO_2.

The emission inventories show that emissions of direct $PM_{2.5}$, SO_2, and NO_X are projected to decrease by 1,371 tpy, 5,832 tpy, and 26,147 tpy, respectively, within the 2-county Southwestern CT Area from the 2007 base year to the end of the maintenance period in 2025. *See* Tables 5 and 6 below. In addition, emissions inventories developed by MARAMA for addressing the 2012 $PM_{2.5}$ NAAQS show that VOC emissions are projected to decrease by about 32,695 tpy and ammonia emissions are projected to decrease by 637 tpy statewide between 2007 and 2020. *See* Table 7 below. While the MARAMA emissions inventories for VOC and ammonia are only projected out to 2020, there is no reason to believe that this downward trend will not continue through 2025. Given that the Southwestern CT Area is already attaining the 1997 annual and 2006 24-hour $PM_{2.5}$ standards with the current level of source emissions, the downward trend in the emissions inventories is consistent with continued attainment. Indeed, projected emissions reductions for the precursors that the state is addressing for purposes of the 1997 and 2006 $PM_{2.5}$ NAAQS indicate that the area should continue to attain both the annual and 24-hour NAAQS following the control strategies that the state has already elected to pursue. Even if VOC and ammonia emissions were to increase unexpectedly between 2020 and 2025, the overall emissions reductions projected in direct $PM_{2.5}$, SO_2, and NO_X would be sufficient to offset any increases. For these reasons, EPA believes that local emissions of all of the potential $PM_{2.5}$ precursors will not increase to the extent that they will cause monitored $PM_{2.5}$ levels to violate the 1997 annual or 2006 24-hour $PM_{2.5}$ standards during the maintenance period.

TABLE 5—NEW HAVEN COUNTY, CT, CHANGE IN EMISSIONS BETWEEN 2007 AND 2025 IN TONS PER YEAR (TPY)

Sector	SO_2 2007–2025	NO^X 2007–2025	$PM_{2.5}$ 2007–2025
Point (EGU)	−424.3	−255.	−4.2
Point (Non-EGU)	3.9	128.9	6.2
Area	−1,030.6	−328.0	−153.9
Marine Vessels, Airplanes, RR Locomotives (MAR)	−691.6	−2,209.7	−117.0
Nonroad (NMIM)	−166.5	−2,084.3	−142.3
Onroad (MOVES)	−17.2	−7,962.6	−203.4
Total	−2,326.3	−12,710.7	−614.7

TABLE 6—FAIRFIELD COUNTY, CT, CHANGE IN EMISSIONS BETWEEN 2007 AND 2025 IN TONS PER YEAR (TPY)

Sector	SO_2 2007–2025	NO_X 2007–2025	$PM_{2.5}$ 2007–2025
Point (EGU)	−1,889.9	−1,160.3	−152.0
Point (Non-EGU)	25.2	668.1	4.9
Area	−1,082.1	−348.7	−163.9
Marine Vessels, Airplanes, RR Locomotives (MAR)	−334.9	−1,688.8	−74.8
Nonroad (NMIM)	−206.4	−2,590.8	−158.9
Onroad (MOVES)	−17.9	−8,315.7	−211.7
Total	−3,505.9	−13,436.2	−756.5

TABLE 7—CONNECTICUT, CHANGE IN EMISSIONS BETWEEN 2007 AND 2020 IN TONS PER YEAR (TPY) [12]

Sector	VOC 2007–2020	Ammonia (NH_3) 2007–2020
Point (nonEGU)	127	0
Point (EGU) [13]	−58	−39
Area	−2,396	55
Non-road mobile	−9,736	5
Commercial Marine Vessels	1	0
Airports	−40	0
Railroad Locomotives	9	0
On-road mobile [13]	−20,602	−658
Total	−32,695	−637

EPA concludes that Connecticut has adequately derived and documented the 2007 attainment year and 2017 and 2025 projected-year emissions of $PM_{2.5}$ and $PM_{2.5}$ precursors, including $PM_{2.5}$, SO_2, NO_X, VOC, and ammonia for the Southwestern CT Area.

b. Maintenance Demonstration

As mentioned above, as required by section 175A of the CAA, Connecticut's June 22, 2012 redesignation request included a 10-year maintenance plan for the Southwestern CT Area. This plan demonstrates maintenance by showing that future emissions of $PM_{2.5}$ and $PM_{2.5}$ precursors remain at or below attainment-year emission levels for both the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. A maintenance demonstration need not be based on modeling. *See Wall* v. *EPA, supra; Sierra Club* v. *EPA, supra. See also* 66 FR at 53099–53100; 68 FR at 25430–32.

Connecticut used 2007 as the base year, 2017 as the interim year, and 2025 as the last year of the maintenance plan. (In addition, per 40 CFR Part 93, a MVEB must be established for the last year of the maintenance plan. MVEBs are discussed in Section V below.) Table 8 shows the emissions inventories for 2007, 2017, and 2025 from Connecticut's June 22, 2012 submittal for the Southwestern CT Area for direct $PM_{2.5}$ and the Area's principal $PM_{2.5}$ precursors, SO_2, and NO_X. The emissions inventory shows a downward trend in $PM_{2.5}$ and $PM_{2.5}$ precursor emissions from 2007 through 2017, and continuing on until 2025. Between 2007 and 2025, emissions are expected to decrease by 43 percent for SO_2, 55 percent for NO_X, and 22 percent for $PM_{2.5}$. As discussed above in the section on ''attainment emissions inventory,'' MARAMA's emissions inventories show that VOC emissions are projected to decrease by about 32,695 tpy and ammonia emissions are projected to decrease by 637 tpy statewide between 2007 and 2020. *See* Table 7 above. While the MARAMA emissions inventories for VOC and ammonia are only projected out to 2020, there is no reason to believe that this downward trend will not continue through 2025.

TABLE 8—COMPARISON OF 2007, 2017, AND 2025 SO_2, NO_X, AND DIRECT $PM_{2.5}$ EMISSION TOTALS FOR THE SOUTHWESTERN CT AREA

[in tpy]

	SO_2	NO_X	$PM_{2.5}$
2007 (attainment)	13,615.9	50,339.1	6,113.0
2017 (interim)	7,909.0	29,501.3	5,029.1
2025 (maintenance)	7,783.7	24,192.2	4,741.7

[12] These emissions estimates are from the emissions inventories developed by MARAMA for use in part in addressing NAAQS requirements for the 2012 $PM_{2.5}$ standards. See Appendix C of Connecticut's June 22, 2012 redesignation request, which is available in the docket for today's rulemaking action.

[13] MARAMA's VOC and NH_3 emission estimates did not include estimates for the EGU and on-road mobile sectors. Emission values in this table represent values taken from EPA's regulatory impact analysis for the PM NAAQS.

TABLE 8—COMPARISON OF 2007, 2017, AND 2025 SO_2, NO_X, AND DIRECT $PM_{2.5}$ EMISSION TOTALS FOR THE SOUTHWESTERN CT AREA—Continued

[in tpy]

	SO_2	NO_X	$PM_{2.5}$
2007 to 2025 (change)	−5,832.2 (−43%)	−26,146.9 (−55%)	−1,371.2 (−22%)

In addition, current air-quality design values (DVs) and air-quality modeling show continued maintenance of both the 1997 annual and 2006 24-hour $PM_{2.5}$ standards during the maintenance period. As shown in Table 9 below, the most recent DVs for the Southwestern CT Area are well below the 1997 annual $PM_{2.5}$ NAAQS of 15 μg/m³ and the 2006 24-hour $PM_{2.5}$ NAAQS of 35 μg/m³.

TABLE 9—AIR-QUALITY ($PM_{2.5}$) DESIGN VALUES (μg/m³) FOR FAIRFIELD AND NEW HAVEN COUNTIES

County	1997 annual NAAQS 2007–2009	1997 annual NAAQS 2008–2010	1997 annual NAAQS 2009–2011	2006 24-hr NAAQS 2007–2009	2006 24-hr NAAQS 2008–2010	2006 24-hr NAAQS 2009–2011
Fairfield	11.3	10.0	9.4	31	28	26
New Haven	11.4	10.3	9.6	31	29	28

The modeling analysis conducted for the Regulatory Impact Analysis for the 2012 $PM_{2.5}$ NAAQS [14] indicates that DVs for the Southwestern CT Area are expected to continue to decline through 2020. In the RIA for the 2012 $PM_{2.5}$ NAAQS, the highest annual DV projected for 2020 is 8.79 μg/m³ for Fairfield County and 8.62 μg/m³ for New Haven County. The highest 24-hour DV projected for 2020 is 22.27 μg/m³ for Fairfield County and 21.78 μg/m³ for New Haven County. Given that precursor emissions are projected to decrease through 2025, it is reasonable to conclude that monitored $PM_{2.5}$ levels in this area will also continue to decrease through 2025.

Thus, EPA believes that there is ample justification to conclude that the Southwestern CT Area should be redesignated, even taking into consideration the emissions of other precursors potentially relevant to $PM_{2.5}$. After consideration of the DC Circuit's January 4, 2013 decision, and for the reasons set forth in this notice, EPA proposes to approve the State's maintenance plan and its request to redesignate the Southwestern CT Area to attainment for the 1997 annual $PM_{2.5}$ standard and for the 2006 24-hour $PM_{2.5}$ standard.

c. Monitoring Network

Connecticut currently operates seven $PM_{2.5}$ monitors in the Connecticut portion of the NY-NJ-CT $PM_{2.5}$ nonattainment area. Three are located in New Haven County, and four are in Fairfield County. In its June 22, 2012 SIP submittal, Connecticut committed to continue to operate all seven of its monitors in accordance with 40 CFR part 58 and to enter all data into the AQS in accordance with federal guidelines. Connecticut has, therefore, addressed the requirement for continued $PM_{2.5}$ monitoring in the Southwestern CT Area.

d. Verification of Continued Attainment

The state has the legal authority to enforce and implement the requirements of the $PM_{2.5}$ maintenance plan. This includes the authority to adopt, implement, and enforce any subsequent emission-control contingency measures determined to be necessary to correct future $PM_{2.5}$ attainment problems. To implement the $PM_{2.5}$ maintenance plan, the state will continue to monitor $PM_{2.5}$ levels in the Southwestern CT Area. Connecticut has also committed to track the progress of the maintenance demonstration by periodically updating its emission inventory. The update will be based, in part, on the annual update of the National Emissions Inventory (NEI), and will indicate new source growth and other changes from the attainment inventory, including any changes in vehicle miles traveled or in traffic patterns.

e. The Maintenance Plan's Contingency Measures

The contingency plan provisions for maintenance plans are designed to promptly correct a violation of the NAAQS that occurs after redesignation. Section 175A of the CAA requires that a maintenance plan include such contingency measures as EPA deems necessary to ensure that a state will promptly correct a violation of the NAAQS that occurs after redesignation. The maintenance plan should identify the events that would ''trigger'' the adoption and implementation of a contingency measure(s), the contingency measure(s) that would be adopted and implemented, and the schedule indicating the time frame by which the state would adopt and implement the measure(s).

As required by section 175A of the CAA, Connecticut's maintenance plan outlines the procedures for the adoption and implementation of contingency measures to further reduce emissions should a violation occur. Connecticut's contingency measures include a Warning Level Response and an Action Level Response. For a Warning Level Response, CT DEEP will track air-quality monitoring data and emission inventories to identify when the Area is at risk of violating either the 1997 annual or 2006 24-hour $PM_{2.5}$ NAAQS. The Warning Level Response will be triggered if either a single year's 98th percentile daily value exceeds 35 μg/m³ or a single year's annual average exceeds 15 μg/m³ at any CT DEEP site in the maintenance area and is verified. CT DEEP will examine available information to identify contributing factors such as atypical meteorological conditions, exceptional events, local changes in source activity, or source malfunctions or noncompliance.

An Action Level Response will be triggered if a verified violation of either $PM_{2.5}$ NAAQS occurs. If an Action Level Response is triggered, as required by

[14] The ''Regulatory Impact Analysis for the Proposed Revisions to the National Ambient Air Quality Standards for Particulate Matter'' is available in the docket for today's rulemaking action.

CAA 175A(d), CT DEEP commits to implementing all measures that were contained in the SIP before the Southwestern CT Area was redesignated to attainment. CT DEEP also commits to pursuing adoption (and submittal to EPA) and implementation of any appropriate regulatory revisions within 18 to 24 months after the verified violation. See letter to EPA dated June 6, 2013, available in the docket for today's action.

CT DEEP will select contingency measures based on cost effectiveness, emission reduction potential, economic and social considerations, or other appropriate factors. Stakeholder input will be solicited before final selection of any contingency measures. Connecticut's candidate contingency measures include, but are not limited to, the following:

- Control measures already adopted, but designed to produce additional reductions after the verified violation occurred (e.g., mobile source measures that involve fleet turnover);
- New control measures that may be adopted for other purposes (e.g., Tier 3 or CALEV3);
- Alternative fuel and/or diesel retrofit programs for fleet vehicle operations;
- New or more stringent $PM_{2.5}$, NO_X or SO_2 controls on stationary sources;
- Wood stove change out program;
- ''No burn'' days during cold weather inversion events;
- Enhanced idle restrictions; and
- Transportation control measures, selected in consultation with Connecticut Department of Transportation (CT DOT) and affected local metropolitan planning organizations (e.g., traffic flow improvements, transit improvements, trip reduction programs, other new or innovative transportation measures).

In addition, NO_X reductions from fleet turnover are happening each year automatically, without any additional rulemaking.

It is unlikely, however, that Connecticut will violate either $PM_{2.5}$ standard. As shown in Table 9 above, the design values in both Fairfield and New Haven Counties are decreasing. The design values for these counties are 9.4 and 9.6 μg/m^3, respectively, compared to an annual standard of 15.0 μg/m^3; they are 26 and 28 μg/m^3, respectively, compared to a 24-hour standard of 35.0 μg/m^3. If either county were to violate one of the $PM_{2.5}$ standards, we would negotiate a timeline and schedule through our regular annual grant negotiations for which we develop priority and commitment (P&C) lists each year.

For the reasons discussed above, EPA believes that the Southwestern CT Area maintenance plan adequately addresses the five basic components of a maintenance plan: Attainment inventory; maintenance demonstration; monitoring network; verification of continued attainment; and a contingency plan. Therefore, EPA is proposing to approve the maintenance plan SIP revision submitted by Connecticut for the Southwestern CT Area as meeting the requirements of CAA section 175A.

V. MVEBs

1. How are MVEBs developed and what are the MVEBs for the Southwestern CT Area?

As part of its June 22, 2012 redesignation request, CT DEEP requested withdrawal of the SIP-approved 2009 motor vehicle emissions budgets (MVEBs) prepared using MOBILE6.2 and approval of 2017 and 2025 MVEBs prepared using MOVES2010. Under the CAA, states are required to submit, at various times, control strategy SIP revisions and maintenance plans for nonattainment areas and for areas seeking redesignation to attainment for a given NAAQS. These emission-control-strategy SIP revisions (*e.g.,* RFP and attainment demonstration SIP revisions) and maintenance plans create MVEBs based on on-road mobile source emissions for the relevant criteria pollutants and/or their precursors, where appropriate, to address pollution from on-road transportation sources. The MVEBs are the portions of the total allowable emissions that are allocated to on-road vehicle use that, together with emissions from all other sources in the area, will provide for attainment, RFP, or maintenance, as applicable. The budget serves as a ceiling on emissions from an area's planned transportation system. Under 40 CFR part 93, a MVEB for an area seeking a redesignation to attainment is established for the last year of the maintenance plan. See the September 27, 2011 notice of direct final approval for a more complete discussion of MVEBs (76 FR 59512).

EPA's substantive criteria for determining the adequacy of MVEBs are set out in 40 CFR 93.118(e)(4). Additionally, to approve a MVEB, EPA must complete a thorough review of the SIP, in this case the $PM_{2.5}$ maintenance plan, and conclude that with the projected level of motor vehicle and all other emissions, the SIP will achieve its overall purpose, in this case providing for maintenance of the 1997 annual and 2006 24-hour $PM_{2.5}$ standards.

EPA's process for determining adequacy of a MVEB consists of three basic steps: (1) Providing public notification of a SIP submission; (2) providing the public the opportunity to comment on the MVEB during a public comment period; and, (3) EPA taking action on the MVEB. The process for determining the adequacy of submitted SIP MVEBs is codified at 40 CFR 93.118.

The availability of the SIP submission with these 2017 and 2025 MVEBs was announced for public comment on EPA's adequacy Web page on November 27, 2012 at: *http://www.epa.gov/otaq/stateresources/transconf/currsips.htm.* The EPA public comment period on adequacy of the 2017 and 2025 MVEBs for the Southwestern CT Area closed on December 27, 2012. EPA did not receive any comments. EPA sent a letter to CT DEEP on January 8, 2013, stating that the 2017 and 2025 MOVES2010 motor vehicle emissions budgets in the June 22, 2012 SIP are adequate for transportation conformity purposes. On February 5, 2013 (78 FR 8122), EPA notified the public through a **Federal Register** notice of adequacy that EPA has found that the 2017 and 2025 MVEBs adequate for transportation conformity purposes. These MVEBs became effective on February 20, 2013. For the Southwestern CT Area, Connecticut must use the MVEBs in any future conformity determination on or after the effective date of the notice of adequacy.

TABLE 10—TRANSPORTATION CONFORMITY BUDGETS FOR THE SOUTHWESTERN CT AREA IN TONS PER YEAR (TPY)

Year	Direct $PM_{2.5}$	NO_X
2017	575.8	12,791.8
2025	516	9,728.1

As shown in Table 10, CT DEEP has determined the 2017 MVEBs for the Southwestern CT Area to be 575.8 tpy for direct $PM_{2.5}$ and 12,791.8 tpy for NO_X. CT DEEP has determined the 2025 MVEBs for the Southwestern CT Area to be 516 tpy for direct $PM_{2.5}$ and 9,728.1 tpy for NO_X. CT DEEP did not provide emission budgets for SO_2, VOC, and ammonia because it concluded, consistent with the presumptions regarding these precursors in the conformity rule at 40 CFR 93.102(b)(2)(v), which predated and was not disturbed by the litigation on the $PM_{2.5}$ implementation rule, that emissions of these precursors from motor vehicles are not significant contributors to the area's $PM_{2.5}$ air quality problem.

EPA issued conformity regulations to implement the 1997 $PM_{2.5}$ NAAQS in July 2004 and May 2005 (69 FR 40004, July 1, 2004 and 70 FR 24280, May 6, 2005, respectively). Those actions were not part of the final rule recently remanded to EPA by the Court of Appeals for the District of Columbia in *NRDC* v. *EPA,* No. 08–1250 (Jan. 4, 2013), in which the Court remanded to EPA the implementation rule for the $PM_{2.5}$ NAAQS because it concluded that EPA must implement that NAAQS pursuant to the PM-specific implementation provisions of subpart 4 of Part D of Title I of the CAA, rather than solely under the general provisions of subpart 1. That decision does not affect EPA's proposed approval of the Southwestern CT Area MVEBs.

First, as noted above, EPA's conformity rule implementing the 1997 $PM_{2.5}$ NAAQS was a separate action from the overall $PM_{2.5}$ implementation rule addressed by the Court and was not considered or disturbed by the decision. Therefore, the conformity regulations were not at issue in *NRDC* v. *EPA*.[15] In addition, as discussed in section IV.A. the New York Metropolitan Area is attaining the 1997 annual $PM_{2.5}$ NAAQS with a 2007–2009 design value of 14.0 $\mu g/m^3$. As shown on Table 9, for the Connecticut portion of this area (i.e., the Southwestern CT Area), the 2007–2009 and 2009–11 design values (DVs) for Fairfield County were 11.3 $\mu g/m^3$ and 9.4 $\mu g/m^3$, respectively. For New Haven County, these values were 11.4 $\mu g/m^3$ and 9.6 $\mu g/m^3$ (see Table 9). All these DVs are well below the annual $PM_{2.5}$ NAAQS of 15 $\mu g/m^3$. The modeling analysis conducted for the RIA for the 2012 PM NAAQS indicates that the DVs for the Southwestern CT Area are expected to continue to decline through 2020. Further, the State's maintenance plan shows continued maintenance through 2025 by demonstrating that NO_X, SO_2, and direct $PM_{2.5}$ emissions continue to decrease through the maintenance period. For VOC and ammonia, RIA inventories for 2007 and 2020 show that both on-road and total emissions for these pollutants are expected to decrease, supporting the state's conclusion, consistent with the presumptions regarding these precursors in the conformity rule, that emissions of these precursors from motor vehicles are not significant contributors to the Area's $PM_{2.5}$ air quality problem and the MVEBs for these precursors are unnecessary. With regard to SO_2, the 2005 final conformity rule (70 FR 24280) based its presumption concerning on-road SO_2 motor vehicle emissions budgets on emissions inventories that show that SO_2 emissions from on-road sources constitute a ''de minimis'' portion of total SO_2 emissions.

2. What are safety margins?

A ''safety margin'' is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. The on-road MVEBs for direct $PM_{2.5}$ emissions given in Table 10 above do not include either re-entrained road dust or construction dust from transportation projects. The on-road mobile source emissions when added to emissions from all other inventory sources (stationary, other mobile (e.g., non-road, marine vessels, airplanes, locomotives) and area sources) result in annual emissions inventories lower than the year 2007 attainment emissions inventory. Hence both the 2017 and 2025 projected emission levels provide a ''safety margin'' relative to total emissions in the 2007 attainment year. CT DEEP has allocated a small portion (i.e., 10%) of the safety margin to both the 2017 and 2025 MVEBs. Even if emissions reached the full level of the safety margin, the area would still demonstrate maintenance since emission levels would equal those in the attainment year.

The transportation conformity rule allows areas to allocate all or a portion of a ''safety margin'' to the area's MVEBs (40 CFR 92.124(a)). The MVEBs requested by CT DEEP contain NO_X and direct $PM_{2.5}$ safety margins for mobile sources in 2017 and 2025 smaller than the allowable safety margins reflected in the total emissions inventory for the Southwestern CT Area. *See* Table 11.

TABLE 11—TRANSPORTATION CONFORMITY BUDGETS FOR THE SOUTHWESTERN CT AREA

Year	$PM_{2.5}$ (tpy)	NO_X (tpy)
2017:		
On-Road Inventory	467.4	10,708.0
Safety Margin vs. 2007	1083.9	20,837.8
10% of Safety Margin	108.4	2,083.8
2017 Conformity Budget	575.8	12,791.8
2025:		
On-Road Inventory	378.9	7,113.4
Safety Margin vs. 2007	1371.3	26,146.9
10% of Safety Margin	137.1	2,614.7
2025 Conformity Budget	516.0	9,728.1

Thus, the State is not requesting allocation to the MVEBs of the entire available safety margins reflected in the demonstration of maintenance. Therefore, even though the State has submitted MVEBs that exceed the projected on-road mobile source emissions for 2017 and 2025 contained in the demonstration of maintenance, the differences between the MVEBs and the projected on-road mobile source emissions are well within the safety margins of the $PM_{2.5}$ maintenance demonstration. Further, once allocated to mobile sources, these safety margins will not be available for use by other sources.

EPA has reviewed the submitted budgets for 2017 and 2025, including the added safety margins using the conformity rule's adequacy criteria found at 40 CFR 93.118(e)(4) and the conformity rule's requirements for safety margins found at 40 CFR 93.124(a). EPA has determined that the area can maintain attainment of the 1997 annual and 2006 24-hour $PM_{2.5}$ standards for the relevant maintenance period with on-road mobile source emissions at the levels of the MVEBs since total emissions will still remain under attainment year emission levels. EPA is, therefore, proposing to approve the MOVES-based MVEBs submitted by Connecticut for use in determining transportation conformity in the Southwestern CT Area.

VI. Proposed Actions

After fully considering the D.C. Circuit's decisions in *EME Homer City* on EPA's CSAPR rule, and *NRDC* v. *EPA* on EPA's 1997 $PM_{2.5}$ Implementation rule, EPA is proposing to approve Connecticut's June 22, 2012 request to redesignate the Connecticut portion of the New York-N. New Jersey-Long Island, NY–NJ–CT Area (i.e., the Southwestern CT Area) from nonattainment to attainment for the 1997 annual and 2006 24-hour $PM_{2.5}$

[15] The 2004 rulemaking addressed most of the transportation conformity requirements that apply in $PM_{2.5}$ nonattainment and maintenance areas. The 2005 conformity rule included provisions addressing treatment of $PM_{2.5}$ precursors in MVEBs. *See* 40 CFR 93.102(b)(2). While none of these provisions were challenged in the NRDC case, EPA also notes that the Court declined to address challenges to EPA's presumptions regarding $PM_{2.5}$ precursors in the $PM_{2.5}$ implementation rule. *NRDC* v. *EPA,* at 27, n. 10.

NAAQS and of the associated maintenance plan, including the 2017 and 2025 MVEBs. EPA is proposing to withdraw the SIP-approved 2009 MVEBs prepared using MOBILE6.2.

EPA is also proposing to approve the base-year emissions inventory for the Southwestern CT Area included in Connecticut's June 22, 2012 submittal as meeting the comprehensive emissions inventory requirements of section 172(c)(3) of the CAA.

VII. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, these proposed actions do not impose additional requirements beyond those imposed by state law and the CAA. For that reason, these proposed actions:

- are not ''significant regulatory actions'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- are not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because a determination of attainment is an action that affects the status of a geographical area and does not impose any new regulatory requirements on tribes, impact any existing sources of air pollution on tribal lands, nor impair the maintenance of ozone national ambient air quality standards in tribal lands.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401 et seq.

Dated: July 9, 2013.

H. Curtis Spalding,

Regional Administrator, EPA New England.

[FR Doc. 2013–17430 Filed 7–18–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0023; FRL–9392–9]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before August 19, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: A contact person, with telephone number and email address, is listed at the end of each pesticide petition summary. You may also reach each contact person by mail at Biopesticides and Pollution Prevention Division (BPPD) (7511P) or Registration Division (RD) (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a

particular entity, consult the person listed at the end of the pesticide petition summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available online at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

New Tolerance

1. *PP 2E8083.* (EPA–HQ–OPP–2012–0791). Interregional Research Project Number 4 (IR–4), IR–4 Project Headquarters, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540, requests to establish tolerances in 40 CFR part 180 for residues of the herbicide linuron, (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea), and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on cilantro, dried leaves at 27 parts per million (ppm); cilantro, fresh leaves at 3.0 ppm; coriander, seed at 0.01; dill, oil at 4.8 ppm; dill, seed at 0.3 ppm; dillweed, dried leaves at 7.1 ppm; dillweed, fresh leaves at 1.5 ppm; horseradish at 0.05 ppm; parsley, dry leaves at 8.3 ppm; parsley, leaves at 3.0 ppm; and pea, dry, seed at 0.08 ppm. Adequate enforcement methods are available for the determination of linuron in plant and animal commodities. A gas chromatography/mass spectroscopy (GC/MS) detection method involves hydrolysis of linuron and all metabolites by alkaline reflux to 3,4-dichloroaniline, followed by distillation of the 3,4-dichloroaniline into an acid solution. A second method involves extraction of linuron and metabolites using methanol and clean-up of the extract by using an ENVI-Carb solid phase extraction (SPE) column, elution of linuron and its metabolites using methanol followed by methanol-toluene, and concentration of the eluate. The eluate is dissolved in methanol, filtered, and analyzed for linuron and its metabolites using reversed phase high pressure liquid chromatography (HPLC) with MS/MS detection. Contact: Laura Nollen, (RD), (703) 305–7390, email address: *nollen.laura@epa.gov.*

2. *PP 3E8170.* (EPA–HQ–OPP–2013–0235). Interregional Research Project Number 4 (IR–4), IR–4 Project Headquarters, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540, requests to establish tolerances in 40 CFR part 180 for residues of the insecticide chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)-carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, in or on fruit, stone, group12, except cherry, chickasaw plum, and damson plum at 4.0 ppm; nut, tree, group 14–12 at 0.04 ppm; papaya at 4.0 ppm; passionfruit at 4.0 ppm; onion, green, subgroup 3–07B at 3.0 ppm; and spice, subgroup19B at 40 ppm. Since chlorantraniliprole and its metabolic degradates are not of toxicological concern, analytical methods are not applicable. Contact: Laura Nollen, (RD), (703) 305–7390, email address: *nollen.laura@epa.gov.*

3. *PP 2F8131.* (EPA–HQ–OPP–2013–0035). E.I. du Pont de Nemours and Co., 1007 Market St., Wilmington, DE 19898, requests to establish tolerances in 40 CFR part 180 for residues of the herbicide rimsulfuron, in or on sorghum, forage; sorghum, grain; and sorghum, stover at 0.01 ppm. The analytical method DuPont-32277 using reversed-phase high-performance liquid chromatography with electrospray ionization and tandem mass

spectroscopy (HPLC/ESI–MS/MS) detection is used to measure and evaluate the chemical rimsulfuron. Contact: Mindy Ondish, (RD), (703) 605–0723, email address: *ondish.mindy@epa.gov.*

4. *PP 2F8132.* (EPA–HQ–OPP–2013–0034). E.I. du Pont de Nemours and Co., 1007 Market St., Wilmington, DE 19898, requests to establish tolerances in 40 CFR part 180 for residues of the herbicide nicosulfuron, in or on sorghum, forage at 0.4 ppm; sorghum, grain at 0.8 ppm; and sorghum, stover at 0.05 ppm. The analytical method DuPont-32277 using reversed-phase HPLC/ESI–MS/MS detection is used to measure and evaluate the chemical nicosulfuron and its metabolite, IN–V9367. Contact: Mindy Ondish, (RD), (703) 605–0723, email address: *ondish.mindy@epa.gov.*

5. *PP 3F8179.* (EPA–HQ–OPP–2013–0476). Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268, requests to establish a tolerance in 40 CFR part 180 for residues of the insecticide methoxyfenozide, including its metabolites and degradates. Compliance with the tolerance levels is to be determined by measuring only the active ingredient: Methoxyfenozide, (3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl) -2-(1,1-dimethylethyl) hydrazide), in or on pineapple at 0.7 ppm. The proposed tolerance is supported by magnitude of residue studies in pineapple. Liquid chromatography-mass spectroscopy (LC–MS/MS) detection methodology is available for tolerance enforcement. Contact: Olga Odiott, (RD), (703) 308–9369, email address: *odiott.olga@epa.gov.*

Amended Tolerance

1. *PP 2E8083.* (EPA–HQ–OPP–2012–0791). Interregional Research Project Number 4 (IR–4), IR–4 Project Headquarters, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540, requests to amend the tolerance in 40 CFR 180.184(c) by deleting the regional tolerance for residues of the herbicide linuron, (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on parsley, leaves at 0.25 ppm. Contact: Laura Nollen, (RD), (703) 305–7390, email address: *nollen.laura@epa.gov.*

2. *PP 3F8152.* (EPA–HQ–OPP–2013–0411). Bayer CropScience, 2 TW Alexander Dr., Research Triangle Park, NC 27709, requests to amend the tolerance in 40 CFR 180.608 for residues of the insecticide spirodiclofen, 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl ester 2,2-dimethylbutanoate, in or on citrus, oil from 20 ppm to 35 ppm. Adequate analytical methodology using LC/MS/MS detection is available for enforcement purposes. Contact: Rita Kumar, (RD), (703) 308–8291, email address: *kumar.rita@epa.gov.*

3. *PP 3F8161.* (EPA–HQ–OPP–2013–0477). BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709–3528, requests to amend the tolerance in 40 CFR 180.666 for residues of the insecticide fluxapyroxad (BAS 700 F), 1*H*-pyrazole-4-carboxamide,3-(difluoromethyl)-1-methyl-*N*-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-, its metabolites, and degradates, in or on fruit, stone, group 12 from 2.0 ppm to 3.0 ppm. Independently validated analytical methods have been submitted for analyzing residues of parent fluxapyroxad (BAS 700 F) plus metabolites M700F008, M700F048, and M700F002 with appropriate sensitivity in/on fruit, stone, group 12 crops, represented by cherry, peach, and plum for which tolerances have been established. Contact: Olga Odiott, (RD), (703) 308–9369, email address: *odiott.olga@epa.gov.*

New Tolerance Exemption

1. *PP 2E8094.* (EPA–HQ–OPP–2013–0265). The Clorox Company (Clorox), 1221 Broadway, Oakland, CA 94612–1888, requests to establish an exemption from the requirement of tolerance for residues of saturated aliphatic acyclic linear primary alcohols, aldehydes, and acids, under 40 CFR 180.940, when used as pesticide inert ingredients (fragrances) in pesticide formulations used on food-contact surfaces when applied/used in indoor residential settings at a maximum rate of 0.025%. Because Clorox is petitioning for an exemption from the requirement of a tolerance, an enforcement analytical method is not needed. Contact: David Lieu, (RD), (703) 305–0079, email address: *lieu.david@epa.gov.*

2. *PP 2E8116.* (EPA–HQ–OPP–2013–0286). OhSo Clean, Inc., 315 Pacific Ave., San Francisco, CA 94111, requests to establish an exemption from the requirement of a tolerance for residues of copper sulfate pentahydrate (Chemical Abstracts Service Registry Number (CAS No.) 7758–99–8), under 40 CFR 180.940(a), when used as a pesticide inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils. An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. Contact: David Lieu, (RD), (703) 305–0079, email address: *lieu.david@epa.gov.*

3. *PP 2F7998.* (EPA–HQ–OPP–2013–0102). Linde Electronics and Specialty Gases, One Greenwich St., Suite 100, Stewartsville, NJ 08886, requests to establish an exemption from the requirement of a tolerance for residues of the insecticide ethyl formate in or on fumigated agricultural commodities. The GC analytical method is available to EPA for the detection and measurement of the pesticide residues. Contact: Cheryl Greene, (BPPD), (703) 308–0352, email address: *greene.cheryl@epa.gov.*

4. *PP* 3*F8149.* (EPA–HQ–OPP–2013–0253). Bayer CropScience LP, Biologics, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709, requests to establish an exemption from the requirement of a tolerance for residues of the insecticide *Streptomyces microflavus,* strain AQ 6121, in or on all agricultural commodities. The petitioner believes no analytical method is needed because it is expected that, when used as proposed, *Streptomyces microflavus,* strain AQ 6121, would not result in residues of toxicological concern. Contact: Michael Glikes, (BPPD), (703) 305–6231, email address: *glikes.michael@epa.gov.*

5. *PP IN–10547.* (EPA–HQ–OPP–2013–0444). Oro-Agri, Inc., 990 Trophy Club Dr., Trophy Club, TX 76262, requests to establish an exemption from the requirement of a tolerance for residues of sweet orange peel tincture (CAS No. 8028–48–6) under 40 CFR 180.910 for pre- and post-harvest crops when used as a pesticide inert ingredient (surfactant and fragrance) when contained at concentrations up to 10% in pesticide formulations and applied to agricultural crops, pre-plant through post-harvest. The petitioner believes no analytical method is needed because this information is not required for the establishment of a tolerance exemption. Contact: Lisa Austin, (RD), (703) 305–7894, email address: *austin.lisa@epa.gov.*

6. *PP IN–10553.* (EPA–HQ–OPP–2013–0284). Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300, requests to establish an exemption from the requirement of a tolerance for residues of polyurethane-type polymers (CAS Nos. 1161844-26-3, 1161844-30-9, 1161844-43-4, 1161844-51-4, 1161844-53-6, 693252-31-2, 162993-60-4, and 630102-86-2), under 40 CFR 180.960, when used as a pesticide inert ingredient (carrier) in or on raw agricultural commodities and

food products. Tolerance exemption descriptors for polymers produced by the reaction of either 1,6-hexane-diisocyanate; 2,4,4-trimethyl-1,6-hexanediisocyanate; 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyI cyclohexane (isophoronediisocyanate); 4,4′- methylene-bis-1, 1′-cyclohexanediisocyanate; 4,4′-methylene-bis-1,1′benzyldiisocyanate; or 1,3-bis-(2-isocyanatopropan-2-yl) benzene with polyethylenglycol and end-capped with one or a mixture of more than one of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, and octadec-9-enol or polyethyleneglycol ethers of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, and octadec-9-enol. An analytical method to determine the molecular weight of the polymer is dynamic light scattering. The petitioner believes no analytical method is needed because this information is not required for the establishment of a tolerance exemption. Contact: William D. Cutchin, (RD), (703) 305–7990, email address: *cutchin.william@epa.gov.*

7. *PP IN–10559.* (EPA–HQ–OPP–2013–0383). Evonik Goldschmidt Corp., P.O. Box 1299, Hopewell, VA 23860, requests to establish an exemption from the requirement of a tolerance for residues of 2,5-furandione, polymer with ethenylbenzene, hydrolyzed, 3-(dimethylamino)propyl imide, imide with polyethylene-polypropylene glycol 2-aminopropyl Me ether, 2,2'-(1, 2-diazenediyl)bis[2-methylbutanenitrile]-initiated, minimum number average molecular weight (in AMU) 5,816 (CAS No. 1062609–13–5), under 40 CFR 180.960, when used as a pesticide inert ingredient (functioning as a dispersant) in pesticide formulations. The petitioner believes no analytical method is needed because this information is not required for the establishment of a tolerance exemption. Contact: David Lieu, (RD), (703) 305–0079, email address: *lieu.david@epa.gov.*

8. *PP IN–10565.* (EPA–HQ–OPP–2013–0467). Huntsman Corp., 8600 Gosling Rd., The Woodlands, TX 77381, requests to establish an exemption from the requirement of a tolerance for residues of cumenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts with no limits when used as pesticide inert ingredients (surfactants, related adjuvants of surfactants) in pesticide formulations under 40 CFR 180.920 and 180.930, in or on all the raw agricultural commodities, including the following with Chemical Abstracts Service Registry Numbers (CASRNs): Benzenesulfonic acid, 4-(1-methylethyl)-, sodium salt (15763–76–5); benzenesulfonic acid, 4-(1-methylethyl)- (16066–35–6); benzenesulfonic acid, 4-(1-methylethyl)-, potassium salt (164524–02–1); benzenesulfonic acid, (1-methylethyl)-, potassium salt (28085–69–0); benzenesulfonic acid, (1-methylethyl)-, sodium salt (1:1) (28348–53–0); benzenesulfonic acid, 2(or 4)-(1-methylethyl)- (28631–63–2); benzene, (1-methylethyl)-, monosulfo deriv., sodium salt (1:1) (32073–22–6); benzenesulfonic acid, (1-methylethyl)-, ammonium salt (1:1) (37475–88–0); benzenesulfonic acid, (1-methylethyl)-(37953–05–2); benzenesulfonic acid, (1-methylethyl)-, magnesium salt (90959–88–9). Prior to the submission of this petition to add cumenesulfonate CASRNs, the EPA reapproved toluenesulfonate and xylenesulfonate hydrotropes in the EPA Decision Documents dated 9/14/2006 and 6/30/2006. The combined documents are available at *http://www.epa.gov/opprd001/inerts/xylenesulfonic.pdf.* Huntsman Corp. is relying on the information in that combined EPA Decision Document to support this petition which includes a chemistry that was also in the Screening Information Data Set (SIDS) Initial Assessment Report for hdrotropes. The SIDS hydrotropes category included cumenesulfonates, toluenesulfonates, and xylenesulfonates. In fact, cumenesulfonate data was used to support the reassessment of the toluenesulfonates and xylenesulfonates in the EPA Decision Document. Huntsman Corp. does not expect the addition of these cumenesulfonate CASRNs to result in additional exposure or risk, and no new data is being submitted with this petition. The petitioner believes no analytical method is needed because this information is not required for the establishment of a tolerance exemption. Contact: William D. Cutchin, (RD), (703) 305–7990, email address: *cutchin.william@epa.gov.*

Amended Tolerance Exemption

1. *PP IN–10544.* (EPA–HQ–OPP–2013–0210). Akzo Nobel Surface Chemistry, LLC, 525 West Van Buren, Chicago, IL 60607–3823, requests to amend an exemption from the requirement of a tolerance under 40 CFR 180.920, 180.930, or 180.960, for residues of [alpha]-alkyl-[omega]-hydroxypoly (oxypropylene) and/or poly(oxyethylene) polymers where the alkyl chain contains a minimum of six carbons, and alkyl-*w*-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons, minimum number average molecular weight (in AMU) 1,100 in or on the raw agricultural commodity growing crops at no limitation. An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. Contact: William D. Cutchin, (RD), (703) 305–7990, email address: *cutchin.william@epa.gov.*

2. *PP IN–10551.* (EPA–HQ–OPP–2013–0381). Akzo Nobel Surface Chemistry, LLC, 909 Mueller Dr., Chattanooga, TN 37406, requests to revise an existing exemption from the requirement of a tolerance for modified acrylic polymers in 40 CFR 180.960. Akzo Nobel Surface Chemistry, LLC, is requesting that the exemption be revised to include lauryl methacrylate by inserting lauryl methacrylate after hydroxyethyl acrylate and before the following text ''and its sodium, potassium, ammonium, monoethanolamine and triethanolamine salts; the resulting polymer having a minimum number average molecular weight (in amu), 1200.'' This entry begins with the following: Styrene, copolymers with acrylic acid. The petitioner believes no analytical method is needed because this information is not required for the establishment of a tolerance exemption. Contact: Mark Dow, (RD), (703) 305–5533, email address: *dow.mark@epa.gov.*

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 11, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013–17378 Filed 7–18–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB DOCKET NO. 13–147; FCC 12–79]

Allegations of Anticompetitive Behavior in Satellite Industry

AGENCY: Federal Communications Commission.

ACTION: Notice of Inquiry.

SUMMARY: The Federal Communications Commission (Commission) seeks comment on whether, and, if so, to what extent, incumbent satellite operators are

inhibiting competition in the market for satellite services, particularly in the fixed-satellite services (FSS) arena. Specifically, the Commission seeks comment on whether FSS operators are warehousing satellite orbital locations and frequency assignments, and preventing competitors from purchasing capacity on incumbent-owned satellites.

DATES: Comments are due on or before August 19, 2013, and reply comments are due on or before September 17, 2013.

ADDRESSES: You may submit comments, identified by IB Docket No. 13–147, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http:///www.fcc.gov/cgb/ecfs*. Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC by email to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.): *FCC504@fcc.gov;* or phone 202–418–0530; or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, *see* the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Alan Thomas (202) 418–2338, Satellite Division, International Bureau, Federal Communications Commission, Washington, DC 20554. For additional information concerning the information collection(s) contained in this document, contact Judith B. Herman at 202–418–0214, or via the Internet at *Judith-B.Herman@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Inquiry (Notice) in IB Docket No. 13–147, adopted June 5, 2013, and released on June 7, 2013. The full text of the Notice is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 202–488–5300, facsimile 202–488–5563, or via email *FCC@BCPIWEB.com*.

Initial Paperwork Reduction Act of 1995 Analysis: This document does not propose revised information collection requirements.

I. Summary of Notice of Inquiry

A. Background

In this *Notice of Inquiry* (*Notice*) the Commission seeks comment on whether, and, if so, to what extent, incumbent satellite operators are inhibiting competition in the market for satellite services, particularly in the fixed-satellite services arena. This *Notice* results from comments submitted in response to two Congressionally-mandated reports: The *Orbit Act Report* and the *Satellite Competition Report*.

Pursuant to the Open-Market Reorganization for the Betterment of International Telecommunications Act (Orbit Act),[1] the Commission is required to submit an annual report to Congress concerning the progress made with regard to the privatization of INTELSAT and Inmarsat. Some of the comments submitted in preparation of the *Eleventh Orbit Act Report*[2] raised two allegations of anticompetitive behavior: First, that Intelsat and other dominant satellite operators are warehousing scarce orbital resources, *i.e.,* hoarding satellite orbital locations and frequency assignments by failing to replace aging satellites on a timely basis or otherwise failing to provide transponder capacity that reflects current technology. The second allegation is that Intelsat is now a vertically integrated company, *i.e.* able to provide its customers both space and ground communications services, that discriminates against competitors. As a vertically integrated company, Intelsat not only provides satellite services to integrators (resellers) who need satellite bandwidth to fashion their own customer-specific service offerings, but Intelsat also competes against integrators because Intelsat is now able to fashion its own customer-specific service offerings. Consequently, some integrators allege that this dual role has resulted in them being vertically foreclosed or barred by Intelsat from securing satellite bandwidth capacity.

The Commission noted that the *Eleventh Orbit Act Report* was not the appropriate forum in which to resolve such allegations, and stated that the allegations would be addressed in an appropriate forum.

The allegations were again raised in comments considered in the *Third Satellite Competition Report,*[3] a report the Commission annually delivers to Congress regarding the state of competition in the satellite industry.[4] In the *Third Satellite Competition Report,* one commenter expanded upon the warehousing and vertical foreclosure allegations it made in the *Eleventh Orbit Act Report;* the Commission, however, determined that it was unable to reach conclusions regarding these allegations for two reasons. First, the factual record for the *Third Satellite Competition Report* was limited with regard to the warehousing allegations and, second, the evidence was inconclusive whether Intelsat restricts or prevents integrators from obtaining satellite bandwidth capacity. The *Third Satellite Competition Report* concluded that these allegations warranted additional analysis in a separate proceeding where a more detailed record could be developed and explored.

B. Warehousing Allegations

a. Gaps in Service

In the *Notice,* the Commission identified four types of potential warehousing scenarios. In the first scenario, warehousing can result from gaps in service when an operator de-orbits or relocates an in-orbit satellite, but does not immediately place another satellite into the vacated orbital location. Whether such a gap is the result of warehousing or a legitimate exercise of operator flexibility is a determination the Commission makes on a case-by-case basis. In the *Notice,* the Commission asks, for example, whether it should adopt a rule that declares unused spectrum available for reassignment as soon as service is terminated, unless an operator can demonstrate that it terminated service because of an unforeseen catastrophic circumstance. Alternatively, the Commission asks whether permitting some gap in service would strike a better balance between providing an operator flexibility in managing its fleet while still safeguarding against warehousing.

Gaps in service often result in satellite operators inserting replacement satellites that do not operate on all the frequency bands used by the retired or relocated satellite; and while satellite operators sometimes specify the frequencies used by both incoming and outgoing satellites, often they do not,

[1] Open-Market Reorganization for the Betterment of International Telecommunications Act, 47 U.S.C. §§ 701, 706(e) (2000).

[2] *FCC Report to Congress as Required by the ORBIT Act: Eleventh Report,* FCC 10–112, 25 FCC Rcd 7834, 7857–7861(2010)

[3] *Third Report and Analysis of Competitive Market Conditions with respect to Domestic and International Satellite Communications Services,* FCC 11–183, IB Docket Nos. 09–16 and IB 10–99, 26 FCC Rcd 17284, 17346–17353 (2011).

[4] Amendment to Communications Satellite Act, Public Law 109–34, 119 Stat. 377 (2005), *codified at* 47 U.S.C. § 703.

thus requiring that the Commission expend resources and time in order to sort out which frequencies are operational at a particular orbital location. Thus, the Commission asks, for example, whether each replacement application should include a table that lists the frequencies used by both the original and the replacement space station, and whether an application should be considered incomplete if it does not include such a table. The Commission also seeks comment on how to expeditiously address situations where incomplete frequency information is provided.

Additionally, there are instances where a gap in service is caused by unforeseen circumstances. Under the Commission's current rules, requests for emergency replacement satellites are considered on a case-by-case basis and, generally, the Commission grants authority for emergency replacement satellites as long as an operator timely launches a new satellite or relocates an in-orbit satellite into the vacant orbital location. Where the failure of a fully functional five-year old in-orbit satellite would be viewed as a catastrophic failure that excuses a gap in service, the Commission asks, for example, whether the same should be true of a fourteen-year old satellite that fails a few months earlier than expected; relatedly, the Commission asks whether in a non-emergency situation, the satellite operator should have made significant progress on construction of and have concrete launch plans for a replacement satellite, particularly given that it takes two-to-five years to construct and launch a satellite. The Commission also asks, for example, whether it should require satellite operators to submit, in their annual reports, end-of-life projections for all in-orbit satellites, and asks for comment on whether it should propose rules that may allow it to expedite consideration of requests for emergency replacement satellites.

b. Older Replacement Satellites

In the second scenario, warehousing can arise when there is no gap in service but a satellite operator decides to relocate an older, in-orbit satellite to serve as a replacement for a satellite it has de-orbited or moved to another location. These situations potentially restrict transponder capacity and result in an underutilization of spectrum resources because newer technology is not brought into use at that orbital location. As with other potential warehousing situations, the Commission must evaluate these requests on a case-by-case basis; thus, the Commission seeks comment on, for example, the use of older satellites as replacement satellites and whether this practice restricts transponder capacity and results in an underutilization of spectrum resources. Additionally, the Commission requests comment on whether or to what extent allowing operators to use older satellites as replacements precludes the use of newer technologies that can provide improved services to consumers.[5] For example, the Commission asks whether it should permit an operator to replace a 13- or 14- year old satellite with another satellite that is 13- or 14-years old, and whether it should be more concerned about the health of the replacement satellite, rather than its age.

c. License Extensions

With an increase in the useful life of satellites, the third potential warehousing scenario is evidenced by the increase in the number of requests made of the Commission to extend a satellite's license term well beyond its initial license term. While it may be possible for a satellite to operate an additional decade or more beyond its original license term, the Commission asks whether lengthy extensions allow inefficient or partially-functioning satellites to block customer access to newer, state-of-the art satellites. Additionally, the Commission asks whether, for example, prior to granting a license extension, it should require the operator to submit information regarding the satellite's health, and how it might apply license extension limitations to non-U.S. licensed satellites granted market access to the United States.

d. Underutilized Satellites

The fourth potential warehousing scenario concerns underutilized satellites. Regardless of age and for a variety of reasons, satellites may not be operating at full capacity. The Commission seeks comment on whether this creates a concern that the operator is warehousing spectrum, and asks whether it should propose a rule that automatically terminates a space station license if the percentage of unused capacity exceeds a certain amount. Even if the authorization for an underutilized satellite is not cancelled, the Commission asks whether, at a minimum, the unused spectrum should be made available for reassignment. Additionally, the Commission asks whether there are instances in which such ''non-use'' may be acceptable.

2. Vertical Foreclosure Allegations

Although some integrators allege that a vertically-integrated Intelsat has foreclosed them from securing satellite bandwidth capacity, the Commission's focus is on protecting competition rather than protecting particular competitors. Thus, loss of business and profits to integrator firms themselves is not considered a public interest harm if end users, *i.e.,* customers and/or consumers, are not harmed.

a. Analytical Framework

In the *Third Satellite Competition Report,* the Commission described a multi-step framework for examining the vertical foreclosure allegations and determining whether end users are being harmed. The framework, for example, seeks to determine: (1) Whether the alleged foreclosure conduct has or might lessen competition by excluding integrators from acquiring bandwidth capacity, and whether integrators have access to adequate alternatives to satellite bandwidth; (2) whether Intelsat has the ability to compete effectively as a provider of satellite services as well the ability to foreclose competitors; (3) whether Intelsat's vertical integration creates procompetitive cost savings and efficiencies likely to be passed on to end users; or, instead, is likely to result in increased price or degraded service quality; (4) whether any resulting efficiencies from vertical integration are likely passed on to end users; and (5) whether the Commission must determine if vertically integrated satellite operators will, to their advantage and to the detriment of integrators, purchase bandwidth from each other, and whether that relationship might have an impact on competition.

b. Issues for Inquiry

In addition to seeking comment on the multi-step framework, the Commission seeks additional information that can help it evaluate adequately the warehousing and vertical foreclosure allegations. For example, the Commission seeks more details on the nature and scope of the alleged

[5] Most satellite operators are required to submit annual reports to the Commission detailing the status of their space stations. Depending on the service, the operator may have to provide the status of satellite construction and expected launch dates, and a detailed description of the utilization of in-orbit satellites, including outages, and any transponders not available for service. *See* 47 CFR §§ 25.142(c), 25.143(e), 25.145(f)(1), 25.146(l), and 25.210(l). The Commission has proposed to consolidate these reporting requirements into a single rule. *See Comprehensive Review of Licensing and Operating Rules for Satellite Services,* FCC 12–117, Notice of Proposed Rulemaking, 27 FCC Rcd 11619 (2012). Comprehensive Review of Licensing and Operating Rules for Satellite Services, Proposed Rules, 77 FR 67172 (Nov. 8, 2012).

foreclosure, asking that commenters detail the time period, the geographic routes involved, the amount and type of bandwidth capacity (Ku-band, C-band, etc.) involved, and the size of the disputed business, either in absolute terms or relative to the size of the excluded integrators' business, the FSS operators' business, or the total demand of the affected customer(s). The Commission asks whether integrators, for example, have viable options other than using satellite bandwidth capacity, whether integrators can launch their own satellites, and how non-satellite bandwidth options compare to service provide by satellite operators.

The Commission asks commenters about various types of pricing information; information that will aid in measuring cost savings and efficiencies that, if any, result from vertical integration; data on why vertical integration does not reduce costs and create efficiencies; data that quantifies the effect of the vertical integration on the services provided to end users (including changes in the number of bidders, the features and quality of service provided by the selected bidder, and bid rates); data on whether Intelsat vertical integration was facilitated by horizontal collusion among satellite operators, and/or whether the vertical integration has enhanced or deterred coordinated interactions among potential bidders; and comment on appropriate remedies that could be implemented by the Commission.

II. Regulatory Impact Conclusion

This *Notice* seeks data which will be used to assess the warehousing and vertical foreclosure allegations. It does not propose any changes to existing rules.

III. Procedural Matters

A. Ex Parte

The proceeding this *Notice* initiates shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

B. Initial Regulatory Flexibility Act

This document does not propose any economic impact on small entities.

C. Initial Paperwork Reduction

This document does not propose new or modified information collection requirements, and does not propose to eliminate any existing information collection requirements.

D. Filing of Comments and Reply Comments

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR §§ 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. When filing comments or reply comments, please reference IB Docket No. 13–147. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://www.fcc.gov/cgb/ecfs/* or the *Federal eRulemaking Portal: http://www.regulations.gov*. Filers should follow the instructions provided on the Web site for submitting comments.
- *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington DC 20554.

People With Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice) or 202–418–0432 (TTY). Contact the FCC to request reasonable accommodations for filing comments (accessible format documents, sign language interpreters, CART, etc.) by email at: *FCC504@fcc.gov;* phone: 202–418–0530 or TTY: 202–418–0432.

IV. Ordering Clauses

Accordingly, *it is ordered* that, pursuant to sections 1, 4(i), 4(j), 4(o), 301, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154 (i)–(j) & (o), 301, and 403, section 1.430 of the Commission's Rules, 47 CFR 1.430, this Notice of Inquiry in IB Docket No. 13–47 *is adopted.*

It is further ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center shall send a copy of this Notice of Proposed Rulemaking, including the initial regulatory flexibility act analysis, to the Chief Counsel for Advocacy of the Small

Business Administration, in accordance with Section 603(a) of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* (1981).

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013–17395 Filed 7–18–13; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket Nos. FWS–R8–ES–2012–0100; FWS–R8–ES–2012–0074; 4500030113]

RIN 1018–AZ21; RIN 1018–AY07

Endangered and Threatened Wildlife and Plants; Endangered Status for the Sierra Nevada Yellow-Legged Frog and the Northern Distinct Population Segment of the Mountain Yellow-Legged Frog, and Threatened Status for the Yosemite Toad

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of the public comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on our April 25, 2013, proposed rule to list the Sierra Nevada yellow-legged frog and the northern distinct population segment (DPS) (populations that occur north of the Tehachapi Mountains) of the mountain yellow-legged frog as endangered species, and the Yosemite toad as a threatened species. We are also reopening the public comment period on our April 25, 2013, proposed rule to designate critical habitat for these species. The 60-day comment period for both proposed rules ended on June 24, 2013. This notice announces reopening of the comment periods to allow all interested parties an additional opportunity to comment on the proposed rules and to submit information on the status of the species and proposed critical habitat. We will consider all comments and information provided by the public during these comment periods in preparation of a final determination on our proposed listings and designation of critical habitat. Accordingly, the final decisions may differ from our proposals. If you submitted comments previously, you do not need to resubmit them because we have already incorporated them into the public record and will fully consider them in preparation of the final rules.

DATES: The comment periods for the proposed rules published April 25, 2013, at 78 FR 24472 and 24516, are reopened. We will consider all comments received or postmarked on or before November 18, 2013. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES:

Document availability: You may obtain copies of the proposed rule and related documents on the Internet at *http://www.regulations.gov* at Docket Number FWS–R8–ES–2012–0100 for the proposed listing and Docket Number FWS–R8–ES–2012–0074 for the proposed critical habitat. You can also obtain copies by mail from the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Comment submission: You may submit written comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R8–ES–2012–0100 (the docket number for the proposed listing rule) or FWS–R8–ES–2012–0074 (the docket number for the proposed critical habitat rule). On the search results page, under the Comment Period heading in the menu on the left side of your screen, check the box next to ''Open'' to locate this document. Please ensure you have found the correct document before submitting your comments. If your comments will fit in the provided comment box, please use this feature of *http://www.regulations.gov,* as it is most compatible with our comment review procedures. If you attach your comments as a separate document, our preferred file format is Microsoft Word. If you attach multiple comments (such as form letters), our preferred format is a spreadsheet in Microsoft Excel.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R8–ES–2012–0100 (if commenting on the proposed listing rule) or FWS–R8–ES–2012–0074 (if commenting on the proposed critical habitat rule); Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all information received on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Request for Information in **SUPPLEMENTARY INFORMATION** for more information).

FOR FURTHER INFORMATION CONTACT: Jan Knight, Deputy Field Supervisor, Sacramento Fish and Wildlife Office, 2800 Cottage Way, Suite W–2605, Sacramento, CA 95825; telephone 916–414–6600; facsimile 916–414–6712. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

On April 25, 2013, we published in the **Federal Register** a proposed rule to list the Sierra Nevada yellow-legged frog and the northern distinct population segment (DPS) (populations that occur north of the Tehachapi Mountains) of the mountain yellow-legged frog as endangered species, and the Yosemite toad as a threatened species (78 FR 24472). Also on April 25, 2013, we published in the **Federal Register** a proposed rule to designate critical habitat for these species (78 FR 24516). The 60-day comment period for both proposed rules ended on June 24, 2013.

Information Requested

We are reopening the public comment period for two proposed rules for the Sierra Nevada yellow-legged frog, the northern distinct population segment (DPS) (populations that occur north of the Tehachapi Mountains) of the mountain yellow-legged frog, and the Yosemite toad. We will accept written comments and information during this reopened comment period on our April 25, 2013, proposed rules to list these species (78 FR 24472) and to designate critical habitat (78 FR 24516). For more information on the specific information we are seeking, please see the April 25, 2013, proposed rules.

You may submit your comments and materials concerning the proposed rules by one of the methods listed in **ADDRESSES**. We will not accept comments sent by email or fax, or to an address not listed in **ADDRESSES**. If you submit a comment via *http://www.regulations.gov,* your entire comment—including your personal identifying information—will be posted on the Web site. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.regulations.gov.*

Comments previously submitted need not be resubmitted, as they will be fully considered in preparation of the final rules. We intend that any final actions

resulting from these proposals be as accurate as possible and based on the best available scientific and commercial data. We will consider information and recommendations from all interested parties. Your comments are part of the public record, and we will fully consider them in the preparation of our final determinations.

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: July 9, 2013.

Rowan J. Gould,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2013–17197 Filed 7–18–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket Nos. FWS–R6–ES–2011–0111; FWS–R6–ES–2012–0108: 4500030113]

RIN 1018–AZ20; RIN 1018–AX71

Endangered and Threatened Wildlife and Plants; 6-Month Extension of Final Determinations on the Proposed Endangered Status and Proposed Designation of Critical Habitat for Gunnison Sage-Grouse

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rules; Reopening of the Comment Period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 6-month extension of the final determination of whether to list the Gunnison sage-grouse *(Centrocercus minimus)* as endangered and designate critical habitat, and announce the reopening of the comment period on the proposed rules to list the species and to designate critical habitat. We are taking this action based on our finding that there is substantial disagreement regarding the sufficiency and accuracy of the available data relevant to our determinations regarding the proposed listing rule, making it necessary to solicit additional information by reopening the comment period for 45 days. Comments previously submitted need not be resubmitted as they are already incorporated into the public record and will be fully considered in the final rules.

DATES: The comment period end date is September 3, 2013. We request that comments be submitted by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES: You may submit comments by one of the following methods:

(1) Electronically: Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter the appropriate Docket No.: FWS–R6–ES–2012–0108 for the proposed endangered status for Gunnison sage-grouse; or FWS–R6–ES–2011–0111 for the proposed designation of critical habitat for Gunnison sage-grouse. You may submit a comment by clicking on ''Comment Now!''

(2) *By Hard Copy: For the proposed endangered status for Gunnison sage-grouse,* submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R6–ES–2012–0108; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

For the proposed designation of critical habitat for Gunnison sage-grouse, submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R6–ES–2011–0111; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Patty Gelatt, Western Colorado Supervisor, U.S. Fish and Wildlife Service, Western Colorado Field Office, 764 Horizon Drive, Building B, Grand Junction, CO 81506–3946; telephone 970–243–2778; facsimile 970–245–6933. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at (800–877–8339).

SUPPLEMENTARY INFORMATION:

Background

On January 11, 2013, we published a proposed rule listing the Gunnison sage-grouse as endangered (78 FR 2486) and a proposed designation of critical habitat for the Gunnison sage-grouse (78 FR 2540) under the Endangered Species Act of 1973, as amended (Act). For a description of previous Federal actions concerning the Gunnison sage-grouse, please refer to the proposed listing rule. We held four public meetings regarding the proposed rule and designation in January and February 2013 and also extended the initial 60-day comment period on these proposals by an additional 21 days, until April 2, 2013 (78 FR 15925, March 13, 2013). We also solicited and received independent scientific review of the information contained in each proposed rule from peer reviewers with expertise in Gunnison sage-grouse or similar species biology, in accordance with our July 1, 1994 peer review policy (59 FR 34270).

Section 4(b)(6) of the Act and its implementing regulation, 50 CFR 424.17(a), requires that we take one of three actions within 1 year of a proposed listing and concurrent proposed designation of critical habitat: (1) Finalize the proposed rules; (2) withdraw the proposed rules; or (3) extend the final determination by not more than 6 months, if there is substantial disagreement among scientists knowledgeable about the species regarding the sufficiency or accuracy of the available data relevant to the determination, for the purposes of soliciting additional data.

During the public comment period, we received multiple comments on the proposed listing and critical habitat designation from scientists with knowledge of the species and others regarding the sufficiency or accuracy of the available data used to support these proposed rulemakings. We also received comments on the proposed rules from scientists with expertise on Gunnison sage-grouse or similar species biology through the peer review process. In particular, commenters raised questions regarding:

(1) *The interpretation of scientific literature in the proposed rulemakings, and scientific literature that we may have overlooked in our analysis.* Specifically, some scientists knowledgeable about the species were concerned with the appropriateness of our interpretation of a study by Aldridge *et al.* (2011) on habitat use by Gunnison sage-grouse near roads and residential developments, and a study by Wisdom *et al.* (2011) which concludes that there are no strongholds for the species. These commenters also suggested that there may be additional, relevant studies that were not analyzed in the proposed rules.

(2) *Gunnison sage-grouse population trends.* Specifically, some scientists

questioned our analysis of the species' population trends in the Gunnison Basin, suggesting we did not account for increasing lek counts and what these scientists consider a low risk of extinction in that population.

(3) *The scope and efficacy of Gunnison County's regulatory mechanisms in addressing threats to Gunnison sage-grouse in the Gunnison Basin.* Specifically, we received comments suggesting that we may have underestimated the extent to which Gunnison County's regulatory mechanisms address residential development and other threats to the species.

(4) *The accuracy of projections about the extent of future residential development within the range of the species.* Specifically, commenters suggested that we may have overestimated the amount of future growth in human populations and development that is expected to occur within the species' range in the Gunnison Basin.

(5) *What constitutes historical habitat and important current habitat for the species.* Specifically, some scientists knowledgeable about the species suggested we may have overestimated the extent of historical Gunnison sage-grouse habitat, and habitat that is important for the species.

As a result of these comments, we find that there is substantial disagreement among scientists knowledgeable about the species regarding the sufficiency and accuracy of the available data that is relevant to our determination of the proposed listing and critical habitat designation. In consideration of these scientific disagreements, we have determined that a 6-month extension of final determinations for these rulemakings is warranted, and are hereby extending the final determinations for 6 months in order to solicit information that will help to clarify these issues and to fully analyze this information. This extension will also allow us to solicit and consider information relating to other substantial disagreements regarding available data that are relevant to our final listing determination. If we determine that listing is warranted, we will designate critical habitat to the maximum extent prudent and determinable.

As noted in the proposed listing rule (78 FR 2486), we were previously required by the terms of a judicially approved settlement agreement to make a final determination on the Gunnison sage-grouse proposed rules no later than September 30, 2013. Therefore, with this 6-month extension, we will make a final determination on the proposed rules no later than March 31, 2014.

Public Comments

We will accept written comments and information during this reopened comment period on our proposed listing for the Gunnison sage-grouse that was published in the **Federal Register** on January 11, 2013 (78 FR 2486), and our proposed critical habitat designation for the Gunnison sage-grouse that was published in the **Federal Register** on January 11, 2013 (78 FR 2540). We will consider information and recommendations from all interested parties. We intend that any final action resulting from these proposals be as accurate as possible and based on the best available scientific and commercial data.

In consideration of the scientific and other disagreements about the data used to support these proposed rulemakings, we are particularly interested in new information and comment regarding:

(1) Whether we have appropriately interpreted the scientific studies cited in the proposed rule, and whether there is additional scientific information we may have overlooked;

(2) Gunnison sage-grouse population trends in each population area;

(3) The scope and effectiveness of regulatory mechanisms enacted by Gunnison County to address threats to the Gunnison sage-grouse;

(4) Projections for future residential development and human population growth within Gunnison sage-grouse range in the Gunnison Basin including portions of Gunnison and Saguache Counties; and

(5) What constitutes historical habitat and important current habitat for the species.

If you previously submitted comments or information on the proposed rule, please do not resubmit them. We have incorporated them into the public record, and we will fully consider them in the preparation of our final determination. Our final determination concerning this proposed listing will take into consideration all written comments and any additional information we received.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section above. We request that you send comments only by the methods described in the **ADDRESSES** section.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rules, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Western Colorado Field Office (see **FOR FURTHER INFORMATION CONTACT**). You may obtain copies of the proposed rules on the Internet at *http://www.regulations.gov* at Docket No. FWS–R6–ES–2012–0108 for the proposed endangered status for Gunnison sage-grouse; or Docket No. FWS–R6–ES–2011–0111 for the proposed designation of critical habitat for Gunnison sage-grouse. Copies of the proposed rules are also available at *http://www.fws.gov/mountain-prairie/species/birds/gunnisonsagegrouse/.* A notice of availability for the draft economic analysis of the proposed designation of critical habitat for the Gunnison sage-grouse will be published in the **Federal Register** in the near future.

Authors

The primary authors of this notice are the staff of the U.S. Fish and Wildlife Service.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: June 26, 2013.

Stephen Guertin,

Deputy Director, U.S. Fish and Wildlife Service.

[FR Doc. 2013–16812 Filed 7–18–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 130528511–3592–01]

RIN 0648–BD31

Fisheries off West Coast States; Pacific Coast Groundfish Fishery Management Plan; Commercial, Limited Entry Pacific Coast Groundfish Fishery; Program Improvement and Enhancement

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: This proposed action would implement revisions to the Pacific coast groundfish trawl rationalization program (program), a catch share program, and includes clarifications of regulations that affect the limited entry trawl and limited entry fixed gear sectors managed under the Pacific Coast Groundfish Fishery Management Plan (FMP). This action proposes to implement trailing actions for the program that either implement original provisions of the program, including quota share (QS) permit application and transfer regulations, increase flexibility or efficiency, or address minor revisions/clarifications.

DATES: Submit comments on or before August 19, 2013.

ADDRESSES: You may submit comments on this document, identified by NOAA-NMFS-2013-0086, by any of the following methods:

- Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2013-0086,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to William W. Stelle, Jr., Regional Administrator, Northwest Region, NMFS, 7600 Sand Point Way NE., Seattle, WA 98115–0070; Attn: Ariel Jacobs.
- *Fax:* 206–526–6736; Attn: Ariel Jacobs.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

Written comments regarding the burden-hour estimates or other aspects of the collection of information requirements contained in this proposed rule may be submitted to William W. Stelle, Jr., Regional Administrator, Northwest Region, NMFS, 7600 Sand Point Way NE., Seattle, WA 98115–0070, and to OMB by email to *OIRA_Submission@omb.eop.gov,* or fax to 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Ariel Jacobs, 206–526–4491; (fax) 206–526–6736; *Ariel.Jacobs@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

In January 2011, NMFS implemented the trawl rationalization program for the Pacific coast groundfish fishery's trawl fleet (*see* 75 FR 78344; Dec. 15, 2010). The program was adopted in 2010 through Amendments 20 and 21 to the FMP and consists of an Individual Fishing Quota (IFQ) program for the shorebased trawl fleet (including whiting and non-whiting fisheries); and cooperative (coop) programs for the at-sea mothership and catcher/processor trawl fleets (whiting only). Since that time, the Pacific Fishery Management Council (Council) and NMFS have been addressing implementation issues as they arise, some of which are the subject of this proposed rule. This proposed action would include the following, by category of (a) implementation of original program, (b) increasing flexibility or efficiency, and (c) minor revisions/clarifications:

(A) Implementation of Original Program

1. Establish quota share (QS) permit application and QS transfer regulations,

(B) Increasing Flexibility or Efficiency

2. Clarify exceptions for lenders from control rules,

3. Change the opt-out requirement for quota pound (QP) deficits,

4. Eliminate double filing of co-op reports (November and March),

5. Revise first receiver site license requirements (FRSL), including site inspection and expiration date,

6. Remove end of the year ban on QP transfers between vessel accounts,

(C) Minor Revisions/Clarifications

7. Remove the term ''permit holder'' from groundfish regulations and replace with ''vessel owner'', ''permit owner'', or ''owner of a vessel registered to a limited entry permit'' as applicable,

8. Revise the process for a permit holder (vessel owner) to change their vessel ownership,

9. Clarify that the processor obligation may be to more than one MS permit,

10. Revise the mothership catcher vessel (MS/CV) endorsement restriction given severability,

11. Clarify sorting requirement for full retention so ''predominant species'' means only one species,

12. Clarify the accumulation limits calculation for compliance with the annual QP vessel limit in vessel accounts,

13. Add a prohibition against failing to establish a new vessel account, following a change in vessel ownership, prior to fishing in the Shorebased IFQ program, and

14. Add a prohibition against landing fish from an IFQ trip to a first receiver without a valid FRSL.

Each of these items is described in greater detail below, including sector(s) of the fishery impacted by the item, rationale for the proposed change, and a discussion of any relevant Council action pertaining to the item.

1. Establish QS Permit Application and QS Transfer Regulations

Proposed implementation of QS transfer regulations would only affect the Shorebased IFQ sector of the Pacific Coast Groundfish fishery. The ability to transfer, after the first two years of the program, QS between participants in the Shorebased IFQ sector was approved under the original provisions of the program (see 75 FR 78344), however due to the Reconsideration of the Initial Allocation of Pacific whiting (whiting) to the Shoreside IFQ and Mothership sectors of the fishery, NMFS delayed QS transfer until January 1, 2014 for all species with the exception of widow rockfish (see 77 FR 45508 and 78 FR 18879). By implementing QS transfer regulations, including an application process for new entrants intending to purchase QS, this proposed action will increase flexibility and efficiency for members of this sector, and provide a pathway for new entrants to establish QS permits/accounts and purchase QS.

The Council selected a preliminary preferred alternative (PPA) at its March 2012 meeting to delay the implementation of QS transfer and

divestiture of QS held in excess of the accumulation limits in the shoreside IFQ sector, as well as severability and divestiture in the Mothership sector, pending resolution of the whiting reconsideration. At its September 2012 meeting, the Council recommended that the QS transfer and divestiture periods for the shoreside IFQ sector begin on January 1, 2014 with the deadline to divest shares in excess of the accumulation limits extended to December 31, 2015, and that MS/CV severability begin on September 1, 2014, with a delay of the deadline to divest endorsements and catch history assignments in excess of the accumulation limits extended to August 31, 2016. Therefore, this rule proposes to further develop the process for QS transfers and applications.

NMFS proposes to add a QS permit application process at § 660.140(d)(2)(iii) that would allow each unique QS permit applicant to submit a complete application form, including a Trawl Identification of Ownership Interest Form, between January 1 and November 30 of each year. This application period aligns with the proposed QS trading period below. Upon approval of a QS permit application, NMFS would issue a QS permit and associated QS account with a starting QS percentage balance of zero for each IFQ and individual bycatch quota (IBQ) species. If a QS permit application were denied, an initial administrative determination (IAD) would be mailed to the applicant, who could then appeal the IAD as described at § 660.25(g), subpart C.

NMFS also proposes regulations to more clearly define the process for transfers of QS percentages. All QS permit owners with a renewed QS permit would be able to permanently transfer percentages of QS to other QS permit owners through their online QS account between January 1 and November 30 of each year. Like QP transfers, any transfer of QS would need to be both initiated by the transferor and accepted by the transferee to be a complete transaction. QS would be transferred in increments to the thousandth of a percent (0.001 percent). Any transfer of QS would be registered in the QS account in the current year, but would not be effective for the purposes of allocating QP until the start of the following year. For example, if QS Permit Owner A sold 1.000 percent of Pacific whiting to QS Permit Owner B, the sale of QS would be effective at the time the transfer was accepted by QS Permit Owner B, but no QP would be associated with the sale (QP cannot be transferred between QS accounts—only to vessel accounts). QS Permit Owner A would continue to receive any allocations of Pacific whiting pounds based on the 1.000 percent sold for the remainder of the year. On November 30 of that year (the end of the QS trading period), if QS Permit Owner B still owned the 1.000 percent of Pacific whiting that he purchased from QS Permit Owner A, the QS permit mailed by NMFS would reflect the updated amount of Pacific whiting owned for the following year, and any QP allocated to that 1.000 percent in the following year would be issued to QS Permit Owner B.

Essentially, the QS permit would reflect the amount of QS owned for the purposes of allocating QP in a current year. Regardless of how many QS transfers are made in a given year by the original owner of QS (as given on the QS permit, effective January 1), the original owner will be allocated the QP associated with those percentages. Not until the start of the following year will the new owner(s) of those percentages have the percentages listed on their QS permit and receive the allocation of QP associated with those percentages in their QS account.

Additionally, revisions are proposed for the regulations at § 660.140(d)(3)(i)(C) and (d)(3)(ii)(B)(*2*) that clarify the renewal of QS permits. Currently, all QS permit owners must renew online through the QS account during the October 1–November 30 renewal period each year. Any QS permit owner who does not renew their permit during the renewal period will have their QS account inactivated, and will not receive any allocations of QP based on their QS percentages. The QS permit owner cannot renew their QS permit until the next October 1–November 30 renewal period. Two changes to these current regulations are proposed: (1) Prohibit the transfer of QS to and from QS permits/accounts that have not been renewed, and (2) implement a paper renewal application process for QS permit owners who did not renew their QS permit online during the October 1—November 30 renewal period. The first proposed change to prohibit the transfer of QS to and from QS permits/accounts that have not been renewed aligns with the current process of inactivating accounts associated with non-renewed QS permits. The second proposed change would allow QS permit owners who did not renew their QS permit online during the previous year's renewal period to submit a paper renewal package (QS permit renewal form and Trawl Identification of Ownership Interest Form) after January 1 of the following year. If the paper QS permit renewal was approved in the current year, the QS permit owner would be able to transfer percentages of QS from the time they renew until November 30 of that year. NMFS would not allocate any QP to the QS account until the following calendar year provided they renew during the October 1 to November 30 renewal period of the current year.

For example, if QS permit owner A failed to renew online for the 2014 calendar year by November 30, 2013, QS permit owner A would not be allocated any 2014 QP, and could not transfer QS. If QS permit owner A renews via paper renewal on February 1, 2014, and is approved, they could transfer QS from the time of approval until November 30, 2014; QS permit owner A would not be allocated any QP for 2014. If QS permit owner A renews online for the 2015 calendar year by November 30, 2014, QS permit owner A would be allocated 2015 QP, and could transfer QS in 2015.

2. Clarify Exceptions for Lenders From Control Rules

This proposed action would only affect the Shorebased IFQ sector of the Pacific Coast Groundfish fishery. This item was addressed by the Council at the March and November 2012 Council meetings. At the March 2012 meeting, the Council recommended language that clarified which entities could qualify for exemption from the control rules in response to questions from fishery participants. Further revisions to the control rules were proposed by the Council at the November 2012 meeting.

The current regulations at § 660.140(d)(4)(iii) define control rules for eight categories of participants, with exceptions to three of the categories (§ 660.140(d)(4)(iii)(E–G)) for ''banks and other financial institutions that rely on QS or IBQ as collateral for loans''. The Council motion proposes to add language to the control rules specifying that to qualify as a bank or financial institution for purposes of this paragraph the entity must be regularly or primarily engaged in the business of lending and not engaged in or controlled by entities whose primary business is the harvest, processing, or distribution of fish or fish products. Additionally, the proposed language would require that any lender that wishes to qualify for the exception, and is not a state or federally chartered bank or other financial institution, must disclose to NMFS the identity and share of interest of any entity with a two percent or more ownership interest in the lender, in a manner similar to what is required for the Trawl Identification of Ownership Interest Form as described at § 660.140(d)(4)(iv). Additional

revisions were proposed to make it clear that lenders could access available QP during foreclosure, thereby reducing lenders' risk, and making it more likely that there will be adequate access to financing, and to best facilitate lending in the fishery by providing lenders with security so that they will not run afoul of the control rules by using QS as collateral, and that lenders will be able to protect their interest in that collateral by preventing sale, lease, or other disposition of the QS, QP, or IBQ in the event of a foreclosure.

Therefore NMFS proposes, in accordance with the Council recommendation, to add subparagraphs (*1*) through (*3*) at § 660.140(d)(4)(iii)(G) that clarify the existing exception for banks and other financial institutions that rely on QS or IBQ as collateral for loans. NMFS proposes that to qualify for this exception, a bank or other financial institution must be regularly or primarily engaged in the business of lending and not engaged in or controlled by entities whose primary business is the harvesting, processing, or distribution of fish or fish products. NMFS further proposes that any entity that is not a state or federally chartered bank or financial institution, must submit a letter requesting the exception, and disclose the identity and interest share of any shareholder with a 2% or more ownership interest in the lender through submission of the Trawl Identification of Ownership Interest Form; NMFS will only accept complete applications. Additionally, NMFS proposes to add the revised exception to paragraph (C) at § 660.140(d)(4)(iii), to remove the existing exception from paragraphs (E) and (F), and to add the clause ''with the exception of those activities allowed under paragraphs C and G'' at the end of paragraphs (A), (B), (D), (E), (F), and (H).

3. Change the Opt-Out Requirement for QP Deficits

This proposed action would only affect the Shorebased IFQ sector of the Pacific Coast Groundfish fishery. This item was addressed by the Council at the March and April 2012 Council meetings. At its April 2012 meeting, the Council recommended changing the opt-out requirement for QP deficits lasting more than 30 days in order to allow vessels to rejoin the fishery after deficits are cleared. Under existing regulations, any vessel with a documented deficit is prohibited from fishing groundfish and is required to cure the deficit within 30 days. If a vessel carries a deficit for more than 30 days and the amount of the deficit is within the carryover allowance, then the vessel can stay within compliance of the program by opting out of the fishery for the remainder of the year. Vessels that do not opt out, but instead incur a violation, are allowed to rejoin the fishery as soon as the deficit is cured. Deficits greater than the carryover allowance must be brought to within the carryover allowance before the 30-day clock expires, or the vessel will incur a violation.

The 30-day clock with the provision allowing vessels to opt-out for the remainder of the year was originally intended to encourage vessels to cover their overages sooner rather than later. A variety of circumstances may arise under which a vessel incurs a deficit. Current regulations give the vessel two choices, each with potentially substantial adverse consequences: (1) Incur a violation, including the penalty, and preserve the opportunity to participate later in the year, or (2) leave the fishery and forgo all remaining opportunity for the year (unused QP might be sold off to other vessels). Vessels that have carried a known deficit for more than 30 days may avoid a violation by opting out of the fishery for the remainder of the year (so long as the deficit is less than the carryover allowance).

As described above, this provision creates a situation in which a vessel that incurs a violation is allowed to continue in the fishery while a vessel that stays in compliance must opt out for the remainder of the year. Furthermore, to date there have been three events where a vessel was in deficit and approached the 30-day time period before covering their deficit. However, none of them opted-out of the fishery and all were able to cover their deficits within 30 days. While vessels have not been using the opt-out provision, it is uncertain whether or not they have had to pay higher prices for QP in order to avoid being forced into the opt-out/violation choice. Some view this situation as inequitable. Therefore NMFS proposes to change the regulations at § 660.140(b)(1)(iii) and (e)(5)(ii)(A) such that once a vessel has cured a deficit, it may rejoin the fishery, without incurring a violation. NMFS also proposes to remove the phrase ''however, the vessel owner must notify OLE of the owner's intent to invoke the carryover provision to cover the deficit'' from the end of paragraph (A). This requirement is no longer necessary because surplus carryover is not credited to vessel accounts until the spring, and therefore vessel owners with a deficit at the end of a calendar year would have no way to cover that deficit with surplus carryover pounds within the 30-day limit. The following table describes the changes proposed by these revisions.

Table 1. Implications of the alternatives for vessels incurring a deficit that is within the carryover allowance.

Situation of Vessels Incurring a Deficit	Status Quo	Alternative
Vessel covers deficit within 30 days	Vessel not in violation. Vessel can re-enter the fishery as soon as deficit is covered.	Vessel not in violation. Vessel can re-enter the fishery as soon as deficit is covered.
Vessel opts out by 30 days and covers deficit later	Vessel not in violation. Vessel must stay out of the fishery the entire year.	Vessel not in violation. Vessel can re-enter the fishery as soon as deficit is covered.
Vessel does not opt out and covers deficit later	Vessel in violation. Vessel can re-enter the fishery as soon as deficit is covered.	Vessel in violation. Vessel can re-enter the fishery as soon as deficit is covered.

Vessels with deficits ***greater than the deficit carryover allowance*** may not avoid a violation by opting out by 30 days.

4. Eliminate Double Filing of Coop Reports

This proposed action would only affect the Mothership (MS) and Catcher/Processor (C/P) sectors of the Pacific Coast Groundfish fishery. This item was addressed by the Council at the March and April 2012 Council meetings. At its April 2012 meeting, the Council recommended eliminating the required annual filing of a preliminary coop report in November, leaving in place the requirement that a final report be submitted in March of the following year.

Currently both MS and C/P coops are required to submit to the Council a preliminary annual report in November and to NMFS a final annual report by March 31 of the following year. Because the fishery is not completed on time for the November meeting and a subsequent final report must be provided by March 31 of the following year, the preliminary report is not necessary. Therefore, NMFS proposes to revise the regulations at § 660.113(c)(3) and at § 660.113(d)(3) to require that both the MS and C/P coops submit an annual, final report to both NMFS and the Council in March of the following year.

5. Revise FRSL Requirements, Including Site Inspection and Expiration Date

This proposed action would only affect the Shorebased IFQ sector of the Pacific Coast Groundfish fishery. This item was addressed by the Council at the March and April 2012 Council meetings. At its April 2012 meeting, the Council recommended making several changes to the FRSL regulations in order to make the application process more efficient, to reduce costs of the program, and to decrease the burden on applicants.

Therefore, NMFS proposes to make the following revisions at § 660.140(f)(5): (1) All FRSL will be valid from the effective date identified on the license until June 30; (2) each FRSL holder must have a site inspection for the site given on the license at least once every three years (instead of annually, as currently required); (3) NMFS may require a site inspection more frequently than once every three years as it deems necessary; (4) NMFS may require the presence of a FRSL holder representative at a site inspection, and a site inspection may not be conducted if the FRSL holder fails to make available such a requested representative at the time of inspection; and (5) NMFS may require changes to the catch monitor (CM) plan, and may require that the FRSL holder demonstrate such changes have been implemented at the site prior to acceptance of the FRSL CM plan, which is a requirement for a complete application for a FRSL.

NMFS also proposes further clarifications to the re-registration process at § 660.140(f)(6). First receivers must submit a re-registration application annually, regardless of whether a site inspection is required in that year. For all FRSL holders who submit a complete re-registration application, NMFS will notify those FRSL holders who will be required to have a site inspection during that year. NMFS will mail a FRSL re-registration application to existing license holders on or about February 1 each year. All FRSL will expire on June 30, and those FRSL holders who want to continue to receive IFQ landings without a lapse in their license and have their re-registered license effective beginning on July 1 must submit their complete re-registration application by April 15. For those FRSL holders who submit a re-registration application after April 15 of a given year, NMFS may not be able to issue the license by July 1 of that year, resulting in a lapse of their current FRSL.

6. Remove End of the Year Ban on QP Transfers Between Vessel Accounts

This proposed action would only affect the Shorebased IFQ sector of the Pacific Coast Groundfish fishery. This item was addressed by the Council at the March and April 2012 Council meetings. At its April 2012 meeting, the Council recommended that the December 15–31 prohibition on QP transfers between vessel accounts be removed. Under current regulations at § 660.140(e)(3)(iii)(B), the transfer of QP between vessel accounts was prohibited from December 15–31 in order to allow NMFS to complete any needed end-of-the-year account reconciliation. However, over 2011 and through the PIE 1 rule (effective January 1, 2012), NMFS developed and implemented an end-of-the-year account reconciliation process that doesn't occur during December 15–31, but occurs early the following year once more complete catch data are available. Therefore, NMFS proposes that the regulations at § 660.140(e)(3)(iii)(B) be revised to remove the December 15–31 ban on QP transfers between vessel accounts.

7. Remove the Term ''permit holder'' and Change to ''vessel owner'', ''permit owner'', or ''owner of a vessel registered to a limited entry permit'' as Applicable

This proposed action would affect all members of the commercial, limited entry Pacific Coast Groundfish fishery. In regulation, the term ''permit holder'' is the owner of a vessel registered to a limited entry permit. This item was addressed by the Council at the March and April 2012 Council meetings. At its April 2012 meeting, the Council recommended that due to confusion among the regulated public regarding who is responsible for regulatory compliance, the term ''permit holder'' should be removed from regulations and replaced by ''vessel owner'' or ''owner of a vessel registered to a limited entry permit.'' In some cases, the regulated public has used the term ''permit owner'' and ''permit holder'' interchangeably, which is not accurate. According to regulations, the permit owner registers their permit to be fished by a particular vessel, causing the vessel owner to be the holder of the permit. ''Permit holder'' and ''vessel owner'' are used interchangeably in regulation while the public uses the term ''permit holder'' and ''permit owner'' interchangeably—causing confusion. In an effort to make the regulations more clear, NMFS proposes to remove the definition for ''permit holder'' at § 660.11, and to replace ''permit holder'' at § 660.25(b)(3)(ii) with ''vessels registered to limited entry permits''; to replace ''permit holder'' with ''vessel owner'' in § 660.25(b)(3)(iv)(C)(4), § 660.25(b)(4) introductory text, § 660.25(b)(4)(iv) introductory text, § 660.25(b)(4)(iv)(A) and (C), § 660.25(b)(4)(v)(D), § 660.25(b)(4)(vi)(B), § 660.25(b)(4)(vii)(A) through (C), (g)(1), in § 660.213(d)(2), and in § 660.231(b)(1); to replace ''permit holder'' with ''vessel holding the permit'' in § 660.25(b)(4)(iv)(B); and, to replace ''permit holder'' in § 660.150(d)(1)(iii)(A)(*1*)(*i*) with ''permit owners''.

8. Revise the Process for a Permit Holder (Vessel Owner) To Change Their Vessel Ownership

This proposed action would affect all members of the commercial, limited entry Pacific Coast Groundfish fishery. This item was addressed by the Council at the March and April 2012 Council meetings. At its April 2012 meeting, the Council recognized that the regulations at § 660.25(b)(4)(iv) do not clearly describe the process for a permit holder (vessel owner) to request a change in vessel ownership. NMFS proposes to revise these regulations to clarify the process for a vessel owner to request a change in vessel ownership through the Fisheries Permits Office (FPO). The request would include a requirement for a copy of the new vessel registration documentation (USCG or state). Based

on this provision and review of the regulations, NMFS proposes to revise and clarify not only the process to change the ownership of a vessel (i.e., change in vessel owner), but also the process to change the permit registered to a vessel and to change the owner of a limited entry permit. NMFS proposes to revise § 660.25(b)(4)(iv), (v), (vii), and (viii) accordingly.

9. Clarify That the Processor Obligation Could Be to More Than One MS Permit

This proposed action would affect all members of the Mothership sector of the commercial Pacific Coast Groundfish fishery. This item was addressed by the Council at the March and April 2012 Council meetings. At its April 2012 meeting, the Council recommended that the regulations regarding the processor obligation should be clarified such that a permit with multiple MS/CV endorsements may obligate each endorsement and associated catch history assignment (CHA) to an MS permit. For example, a trawl permit with two MS/CV endorsements could obligate each endorsement to a different MS permit. Each distinct MS/CV endorsement and associated CHA may only be obligated to one MS permit.

This clarification is a logical extension of allowing multiple endorsements to be registered to a single permit and of the regulations at § 660.150(c)(2)(i)(A) on annual MS sector sub-allocations and at § 660.150(g)(2)(iv)(D) on multiple MS/CV endorsements that allow a permit with multiple MS/CV endorsements and associated CHAs to be registered to more than one coop or to both the coop and non-coop fishery (76 FR 74725, published on December 1, 2011). Therefore, NMFS proposes to revise regulations at § 660.150(c)(7)(i) in order to clarify that the processor obligation could be to more than one MS permit. Additionally, NMFS proposes to revise regulations at § 660.150(g)(2)(iv)(D) in order to clarify the process for a permit with multiple MS/CV endorsements that intends to participate in the non-coop fishery. NMFS also proposes to revise regulations at § 660.25(b)(3)(vii) to remove MS/CV endorsements from the list of endorsements that cannot be transferred separate from the limited entry permit.

10. Revise MS/CV Endorsement Restriction Given Severability

This proposed action would affect all members of the Mothership sector of the commercial Pacific Coast Groundfish fishery. This item was not discussed at a Council meeting, but is a minor revision to the regulations proposed by NMFS. The final Reconsideration of the Allocation of Whiting Rule (78 FR 18879) was effective on April 1, 2013 and allowed limited entry trawl permit holders in the Mothership fishery to request a change (or transfer) of MS/CV endorsement and its CHA beginning September 1, 2014 and required MS/CV-endorsed limited entry trawl permit owners to divest themselves of ownership in permits in excess of the accumulation limits by August 31, 2016. NMFS proposes to revise regulations at § 660.25(b)(3)(vii) to remove MS/CV endorsements from the list of endorsements that cannot be transferred separate from the limited entry permit.

11. Clarify Sorting Requirement for Full Retention so ''predominant species'' Means Only One Species

This proposed action would affect the Pacific Coast Groundfish trawl fishery. This item was not discussed at a Council meeting, but is a minor revision to the regulations proposed by NMFS. Currently, the sorting and weighing requirements for full retention fisheries are not clear regarding use of the term ''predominant species''. Currently the regulations at § 660.112(b)(2)(ii), § 660.130(d)(2)(i), § 660.140(j)(2)(viii), and § 660.140(j)(2)(ix) specify sorting requirements for fish processed by IFQ first receivers. Generally catch must be sorted prior to first weighing, however there is an exception provided to vessels declared into the Shorebased IFQ Program such that they may weigh catch prior to sorting, and then all but the ''predominant species'' must be reweighed. Use of the term ''predominant species'' has created confusion because ''species'' may be interpreted to be singular or plural, however as the term is used in this exception, there can only be a single predominant species identified prior to re-weighing, post-sorting, or it becomes extremely difficult to derive the weight of the predominant species by deducting the combined weight of incidental catch from total catch weight. This exception is also provided to the at-sea sectors of the Pacific whiting fishery at § 660.130(d)(3)(i). For fish processed by Pacific whiting at-sea processing vessels, these regulations specify that catch may be weighed prior to sorting and that then all but the predominant species must then be reweighed. The use of ''predominant species'' in this section of regulations should also refer to a single predominant species for the reasons described above for the Shorebased IFQ Program.

Therefore, ''predominant species'' should refer to a single species, for example in the case of whiting directed trips, it should refer to Pacific whiting. NMFS proposes to revise the regulations at § 660.112(b)(2)(ii), § 660.130(d)(2)(i), § 660.130(d)(3)(i), § 660.140(j)(2)(viii), and § 660.140(j)(2)(ix) to clarify that the term ''predominant species'' refers to a single species.

In reviewing the associated regulatory paragraphs on sorting requirements, it was discovered that PIE 1 (which revised the sorting/weighing requirement for non-whiting IFQ) failed to revise this paragraph. NMFS also proposes a minor revision at § 660.12(a)(8) to remove the reference to ''Pacific whiting sectors'' because the exception applies to non-whiting IFQ as well. This is a minor change resulting from an oversight in PIE 1 (*see* 76 FR 54888). NMFS also proposes to revise § 660.130(d)(2)(ii) for this same reason and remove ''Pacific whiting'' from before ''IFQ trip''.

12. Clarify Accumulation Limits Calculation for Compliance With the Annual QP Vessel Limit in Vessel Accounts

This proposed action would affect the Shorebased IFQ sector of the Pacific Coast Groundfish fishery. This item was not discussed at a Council meeting, but is a minor revision to the regulations proposed by NMFS. The current description of how annual QP vessel limits are tracked is misleading. NMFS proposes to revise regulations at § 660.140(e)(4)(i) to clarify that the QP counted toward the annual allowable vessel limit is calculated as all QP transferred into a vessel account less all QP transferred out of a vessel account; pending transfers are not included in this calculation until the transaction has been finalized. The method for calculating the annual vessel limit must be independent of catch (used QP) because vessel accounts in deficit could potentially exceed the vessel limit. The calculation for daily vessel limits (unused QP vessel limits) remains the same.

13. Add a Prohibition Against Failing To Establish a New Vessel Account Following a Change in Vessel Ownership and Prior to Fishing in the Shorebased IFQ Program

This proposed action would affect the Shorebased IFQ sector of the Pacific Coast Groundfish fishery. This item was not discussed at a Council meeting, but is a minor revision to the regulations proposed by NMFS. Current regulations at § 660.140(e)(2)(ii) and (e)(3)(ii) state that any change in vessel ownership, including a change in the legal name of the vessel owner(s), will require the new

owner to register with NMFS for a vessel account. When the owner of a vessel changes, the new owner must request a new vessel account in their name and acquire QP, and may not fish against QP in the old owner's vessel account. Consistent with these regulations, NMFS proposes to add a corresponding prohibition at § 660.112(b) against failing to establish a new registered vessel account in the name of the current vessel owner following a change in ownership of a vessel and prior to fishing in the Shorebased IFQ Program with that vessel.

14. Add a Prohibition on Landing Fish From an IFQ Trip to a First Receiver Without a Valid FRSL

This proposed action would affect the Shorebased IFQ sector of the Pacific Coast Groundfish fishery. This item was not discussed at a Council meeting, but is a minor revision to the regulations proposed by NMFS. Current regulations at § 660.140(f)(1) state that the FRSL authorizes the holder to ''to receive, purchase, or take custody, control, or possession of an IFQ landing.'' Consistent with this regulation, NMFS proposes to add a corresponding prohibition at § 660.112(b) against landing groundfish taken and retained during an IFQ trip, from the vessel that harvested the fish, to a first receiver that does not hold a valid first receiver site license for the physical location where the IFQ landing occurred.

Classification

Pursuant to section 304(b)(1)(A) of the MSA, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Pacific Coast Groundfish FMP, other provisions of the MSA, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

A Regulatory Impact Review (RIR) was prepared on the action in its entirety and is included as part of the initial regulatory flexibility analysis (IRFA) on the proposed regulatory changes. The IRFA and RIR describe the impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A copy of the IRFA is available from NMFS (see **ADDRESSES**) and a summary of the IRFA, per the requirements of 5 U.S.C. 603(a), follows:

These regulations are largely administrative in nature and their economic effects are minor in the context of the entire program. In sum, in addition to minor clarifications to terms used within the existing regulations and minor changes in existing application and renewal processes, these proposed regulations: (1) Establish the administrative QS application and trading processes that support the quota share trading regulations that already have been established; (2) reduce the annual reporting burden on the two at-sea coops—instead of providing a preliminary report and final report, the only requirement is to provide a final report; (3) reduce the annual reporting burden on First Receivers as the mandatory scheduling of First Receiver Site License inspection is being shifted from an annual inspection cycle to a triennial cycle unless issues arise; (4) provide an additional two weeks to IFQ fishermen to trade their QPs; (5) increase fishermen's flexibility by allowing fishermen that opt out of the fishery for the year, a chance to return to the fishery in that same year should they resolve their deficits; and, (6) increase the availability of loans to fishermen by providing non-traditional lenders increased opportunity to make additional loans should they be inhibited by the ownership and control limits.

This proposed action includes regulations that implement the original program, increase the flexibility of the program, or make minor revisions/clarifications to the regulations. Relative to the other regulations being proposed, the following will have an impact on the operation of the fishery. The proposed regulations include the administrative processes that implement QS transfer regulations that already have been established. These processes facilitate the trading of QS so that major benefits of the Program can be achieved. (The major economic benefits of this Program are described at 75 FR 78365.) The regulatory reporting burden of existing regulations is being reduced. The mandatory scheduling of First Receiver Site License inspection is being shifted from an annual inspection cycle to a triennial cycle unless issues arise. The annual reports required by each of the two at-sea co-ops reduced from two reports to one per year. Fishermen are being given more time to fish and more options to resolve any deficits they incur. Current rules include a process by which fishermen can opt-out of the fishery for the year when faced with a deficit in their accounts. This process is revised to allow fishermen to re-enter the fishery within the year if they have resolved their deficit though the transfer of additional QPs into their vessel account. To facilitate NMFS' end of the year reconciliation processes, there was a ban on trading QPs from December 15 to December 31. Because it has confidence in its accounting system, NMFS is now lifting this ban so QPs can be traded all year round. The proposed regulations enhance the ability of non-traditional lenders to provide loans to the industry. To prevent excessive control of quota shares or quota pounds by a participant, NMFS developed various regulations. Within these regulations, exceptions were made for banks or financial institutions that are state or federally chartered as these entities are expected to be regularly or primarily engaged in the business of lending and not engaged in or controlled by entities whose primary business is the harvesting, processing, or distribution of fish or fish products. However, there are non-traditional financial institutions such as non-profit revolving loan programs that are not state or federally chartered. These regulations propose a process where, on a case-by-case basis, these non-traditional lenders can request an exception to the control limits.

While this rule has minor clarifications that affect all limited entry permit holders and vessels, this rule mainly affects the following sectors/programs: Shorebased Individual Fishing Quota (IFQ) Program—Trawl Fishery, Mothership Coop (MS) Program—Whiting At-sea Trawl Fishery, and Catcher-Processor (C/P) Coop Program—Whiting At-sea Trawl Fishery. The Shorebased IFQ fishery is managed with individual fishing quotas for most groundfish species, including whiting. Annually, QP are allocated from the shorebased sector allocation based on the individual QS of each QS owner. (QP is expressed as a weight and QS is expressed as a percent of the shorebased allocation for a given species or species group.) QP may be transferred from a QS account to a vessel account or from one vessel account to another vessel account. Vessel accounts are used to track how QP is harvested since QP is used to cover catch (landings and discards) by limited entry trawl vessels of all IFQ species/species groups. Shorebased IFQ catch must be landed at authorized first receiver sites. The IFQ whiting QS were allocated to a mixture of limited entry permit holders and shorebased processors. One non-profit organization received QS based on the ownership of multiple limited entry permits. The MS coop sector can consist

of one or more coops and a non-coop subsector. For a MS coop to participate in the Pacific whiting fishery, it must be composed of MS catcher-vessel (MS/CV) endorsed limited entry permit owners. Each permitted MS coop is authorized to harvest a quantity of whiting based on the sum of the catch history assignments for each member's MS/CV endorsed permit identified in the NMFS accepted coop agreement for a given calendar year. Each MS/CV endorsed permit has an allocation of whiting catch based on its catch history in the fishery. The catch history assignment (CHA) is expressed as a percentage of whiting of the total MS sector allocation. Currently the MS sector is composed of only a single coop. The C/P coop program is a limited access program that applies to vessels in the C/P sector of the Pacific whiting at-sea trawl fishery and is a single voluntary coop. Unlike the MS coop regulations where multiple coops can be formed around the CHAs of each coop's member's endorsed permit, the single C/P coop receives the total Pacific whiting allocation for the C/P sector. Only C/P endorsed limited entry permits can participate in this coop. The Shorebased IFQ Program is composed of 138 QS permits/accounts, 144 vessel accounts, and 51 first receivers. The MS coop fishery is composed of six mothership processor permits and 35 MS/CV endorsed permits The C/P coop is composed of 10 catcher-processor permits. In 2012, these fleets generated about $79 million in ex-vessel revenue: $11 million by the MS sector, $16 million by the CP sector, and $52 million by the Shorebased IFQ Program.

This proposed rule also proposes changes concerning exemptions for lenders from the control rules and revisions to the opt-out provisions. In Amendment 20 to the FMP, limits (by species group and area) on the amount of QS an individual can control (i.e. control limits) and limits on the amount of QPs that may be registered to a vessel for use in a given year (i.e. accumulation limits—sometimes referred to as species caps). The intent of these limits is to prevent excessive control of QS or QP by a participant. The MSA specifically requires the establishment of a maximum share that each limited access privilege holder is permitted to hold, acquire, or use. In defining the term ''control'' banks and other financial institutions were excluded. Although banks and other financial institutions may rely on QS or IBQ as collateral for loans they are not expected to restrict any activity related to QS, QP, or IBQ in ways that constitute ''control.'' However, there is concern about both whether the entities qualifying for this exception are sufficiently defined-especially for non-traditional lenders such as nonprofit revolving loan funds.

Public comment received from the California Fisheries Fund (CFF) illustrates the issue (*http://www.pcouncil.org/wp-content/uploads/E7c_PC_NOV2011BB.pdf*). ''We have already begun to make loans to participants in the groundfish trawl IFQ fishery for vessel purchase and upgrades and gear upgrades/modifications. Two of our loans (one for vessel upgrades and one for gear purchase) are secured in part by QS. We expect to make further loans for quota leasing/acquisition and to aid young new participants in entering the fishery. Many of these loans will likely be secured (in whole or in part) with quota shares or quota pounds as collateral. Unfortunately, proposed language under consideration by the Council exempts only state- and federally-chartered institutions from the control caps. This language would not allow CFF, RSF Social Finance (*www.rsfsocialfinance.org*) and perhaps other likely lenders to avail themselves of the safe harbor. We are concerned that our lending would be seriously curtailed by such language. While we are concerned about exceeding the control cap generally, CFF would be even more likely to exceed the control cap on a species-by-species basis. Since not all permits were allocated quota on an equal basis, as few as 2 permits pledged as collateral could push us over those species caps. A good example of this is Yelloweye rockfish—several permits appear to have been allocated more than 1% QS and the control cap is only 2.6%.''

Given the nature and variety of financial institutions, it is difficult to develop an explicit exception that encompasses non-traditional lenders. Therefore, NMFS is proposing an exception process for financial institutions that are not banks. A bank or financial institution is defined as a state or federally chartered entity that must be regularly or primarily engaged in the business of lending and not engaged in or controlled by entities whose primary business is the harvesting, processing, or distribution of fish or fish products. Any non-bank entity that wishes to qualify for this exception must submit a letter requesting the exception and a Trawl Identification of Ownership Interest Form. All shareholders that have a two percent or more ownership interest share in the lender must be identified. The lender must make subsequent annual submissions of the Trawl Identification of Ownership Interest Form to maintain the exception.

The proposed action to change the opt-out requirement for QP deficits would only affect the Shorebased IFQ sector of the Pacific Coast Groundfish fishery. NMFS is proposing changes to the ''opt-out'' requirements because inequities between a vessel that incurs a violation and is allowed to continue in the fishery compared to a vessel that stays in compliance and opts-outs for the remainder of the year-relying on future carryover pounds to resolve any deficit. The changes to the opt-requirements allow vessels that opt out the ability to return to the fishery if at some time during the year, the vessel resolves its deficit issue. This item was addressed by the Council at the March and April 2012 Council meetings. At its April 2012 meeting, the Council recommended changing the opt-out requirement for QP deficits lasting more than 30 days, in order to allow vessels to rejoin the fishery after deficits are cleared. Under the status quo, any vessel with a documented deficit is prohibited from fishing groundfish and is required to cure the deficit within 30 days. If a vessel carries a deficit for more than 30 days and the amount of the deficit is within the carry-over allowance, then the vessel can stay within compliance of the program by opting out of the fishery for the remainder of the year. Vessels which do not opt out, but instead incur a violation, are allowed to rejoin the fishery as soon as the deficit is cured. Deficits greater than the carryover allowance must be brought within the carryover allowance before the 30-day clock expires, or the vessel will incur a violation.

A variety of circumstances may arise under which a vessel incurs a deficit. When a deficit is incurred early in the year, it may not be possible to acquire QP for certain species at a reasonable price because of uncertainties about bycatch rates and tight QP markets for constraining species. Later in the year, QP could become more readily available. However, current regulations give the vessel two choices, each with potentially substantial adverse consequences: (1) Incur a violation, including the penalty and subsequent consequences of a violation record, and preserve the opportunity to participate later in the year, or (2) leave the fishery and forgo all remaining opportunity for the year (unused QP might be sold off to other vessels). Vessels that have carried a known deficit for more than 30 days may avoid a violation by opting out of the fishery for the remainder of

the year (so long as the deficit is less than the carryover allowance). The 30-day clock with the provision allowing vessels to opt-out for the remainder of the year was originally intended to encourage vessels to cover their overages sooner rather than later.

However, as described above, this provision creates a situation in which a vessel that incurs a violation is allowed to continue in the fishery while a vessel that stays in compliance must opt out for the remainder of the year. Furthermore, to date there have been three events where a vessel was in deficit and approached the 30-day time period before covering their deficit. In two of these cases the deficit involved target species, and the vessel did not cover the deficit because it was participating in another fishery and chose to wait until the end of the 30-day period before covering their deficit. In the third situation, the deficit involved a large quantity of an overfished species. In all three situations the deficits were larger than the carryover amount (10 percent) and the vessels were not eligible to opt out. While vessels have not been using the opt-out provision, it is uncertain whether or not they have had to pay higher prices for QP in order to avoid being forced into the opt-out/violation choice. Some view this situation as inequitable. In order to correct this perceived inequity, NMFS proposes to change the regulations at § 660.140(e)(5)(ii)(A) so that once a vessel has cured a deficit, it may rejoin the fishery without incurring a violation.

The Small Business Administration has established size criteria for all major industry sectors in the US, including fish harvesting and fish processing businesses. A business involved in fish harvesting is a small business if it is independently owned and operated and not dominant in its field of operation (including its affiliates) and if it has combined annual receipts not in excess of $4.0 million for all its affiliated operations worldwide. A seafood processor is a small business if it is independently owned and operated, not dominant in its field of operation, and employs 500 or fewer persons on a full time, part time, temporary, or other basis, at all its affiliated operations worldwide. A business involved in both the harvesting and processing of seafood products is a small business if it meets the $4.0 million criterion for fish harvesting operations. A wholesale business servicing the fishing industry is a small business if it employs 100 or fewer persons on a full time, part time, temporary, or other basis, at all its affiliated operations worldwide. For marinas and charter/party boats, a small business is one with annual receipts not in excess of $7.0 million. These regulations also affect a class of financial institutions. NMFS believes that the following standard applies for All Other Non-depository Credit Intermediaries—$6 million in average annual receipts as the maximum annual receipts for small entities.

As part of the permit application processes for the non-tribal fisheries, based on a review of the SBA size criteria, applicants are asked if they considered themselves a ''small'' business and to provide detailed ownership information. Many companies participate in two or more of these sectors. All MS/CV participants are involved in the shorebased IFQ sector while two of the three CP companies also participate in both the shorebased IFQ sector and in the MS sector. Many companies own several QS accounts or own vessel accounts. Taking into account cross participation, multiple accounts, and affiliation between entities, NMFS estimates that there are 143 fishery related entities directly affected by these proposed regulations, 99 of which are considered to be ''small'' businesses.

NMFS is not familiar with the financial industry; the following is a tentative projection of the potential number of small lenders affected by this rule. Public comment received by the PFMC indicates that there are possibly two lenders that are the most likely lenders to apply for the lender's exception. Based on SBA criteria and review of information associated with these lenders, both these lenders can be considered ''large'' entities based on either the amount of their business activities or by their affiliation with large entities. However, there are a number of small lenders that may qualify for the ''exception.'' A review of the North American Industry Classification System used by the U.S. Census Bureau suggests that the likely entities that may seek an exception fall into the ''NAICS 522298-All Other Non-depository Credit Intermediation'' category. This category includes lenders that, for example, provide short-term inventory, credit, agricultural lending, and consumer cash lending secured by personal property. U.S. Census data indicates that in 2011, there were 730 entities within the NAICS 522298 classification operating in the states of Washington, Oregon, and California—the states most likely to have lenders that will work with the West Coast industry. In assessing various lenders that participate in SBA programs that fall within the NAICS 522298 classification, SBA estimated that over 95 percent of these participants did not exceed the applicable small business size standard and are, therefore to be considered small entities (73 FR 75507; December 11, 2008). Applying this percentage suggests that there are approximately 695 small lenders in the states of Washington, Oregon, and California that are potential beneficiaries of this rule.

As this proposed rule is primarily administrative in nature, NMFS does not believe that the proposed changes would have a significant impact on small entities; these changes were recommended by the industry to increase flexibility or efficiency. As such, NMFS has not identified significant alternatives. Through the rulemaking process associated with this action, we are requesting comments on this conclusion.

No Federal rules have been identified that duplicate, overlap, or conflict with the alternatives. Public comment is hereby solicited, identifying such rules. A copy of this analysis is available from NMFS (see **ADDRESSES**).

This proposed rule contains a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been submitted to OMB for approval. Public reporting burden for the QS permit/account application form is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Public reporting burden for the online QS transfer form is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Public reporting burden for the online QP transfer form (from a QS account to a vessel account, or vessel account to another vessel account) is estimated to average 8 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Public reporting burden for the trawl identification of ownership interest form for new entrants, including lenders, is estimated to average 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data

needed, and completing and reviewing the collection of information. Public reporting burden for the first receiver site license application form for re-registering applicants is estimated to average 110 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Public reporting burden for the mothership cooperative permit application form is estimated to average 4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Public reporting burden for the catcher/processor cooperative permit application form is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to NMFS, Northwest Region at the **ADDRESSES** above, and email to *OIRA_Submission@omb.eop.gov,* or fax to 202–395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

This proposed rule was developed after meaningful consultation and collaboration, through the Council process, with the tribal representative on the Council. The proposed regulations have no direct effect on the tribes.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, and Indian fisheries.

Dated: July 11, 2013.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, performing the functions and duties of the Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons stated in the preamble, 50 CFR part 660 is proposed to be amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 is revised to read as follows:

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

§ 660.11 [Amended]

■ 2. In § 660.11, remove the definition for ''Permit holder''.

■ 3. In § 660.12, revise paragraph (a)(8) to read as follows:

§ 660.12 General groundfish prohibitions.

* * * * *

(a) * * *

(8) Fail to sort, prior to the first weighing after offloading, those groundfish species or species groups for which there is a trip limit, size limit, scientific sorting designation, quota, harvest guideline, ACT, ACL or OY, if the vessel fished or landed in an area during a time when such trip limit, size limit, scientific sorting designation, quota, harvest guideline, ACT, ACL or OY applied; except as specified at § 660.130(d).

* * * * *

■ 4. In § 660.25 revise paragraphs (b)(3)(ii), (b)(3)(iv)(C)(*4*), (b)(3)(vii), (b)(4) introductory text, add paragraph (b)(4)(i)(G), revise paragraphs (b)(4)(iv) introductory text, (b)(4)(iv)(A) through (C), (b)(4)(v)(B) and (D), (b)(4)(vi)(B), (b)(4)(vii) introductory text, (b)(4)(vii)(A) through (C), (b)(4)(viii), and (g)(1) to read as follows:

§ 660.25 Permits.

* * * * *

(b) * * *

(3) * * *

(ii) *Gear endorsement.* There are three types of gear endorsements: Trawl, longline and pot (trap). When limited entry ''A''-endorsed permits were first issued, some vessel owners qualified for more than one type of gear endorsement based on the landings history of their vessels. Each limited entry ''A''-endorsed permit has one or more gear endorsement(s). Gear endorsement(s) assigned to the permit at the time of issuance will be permanent and shall not be modified. While participating in the limited entry fishery, the vessel registered to the limited entry ''A''-endorsed permit is authorized to fish the gear(s) endorsed on the permit. While participating in the limited entry, fixed gear primary fishery for sablefish described at § 660.231, a vessel registered to more than one limited entry permit is authorized to fish with any gear, except trawl gear, endorsed on at least one of the permits registered for use with that vessel. Vessels registered to limited entry permits may be used to fish with open access gear, subject to the crossover provisions at § 660.60 (h)(7)(ii), except that vessels registered to sablefish-endorsed permits fishing in the sablefish primary season described at § 660.231, may not fish with open access gear against those limits. An MS permit does not have a gear endorsement.

* * * * *

(iv) * * *

(C) * * *

(*4*) Any partnership or corporation with any ownership interest in a limited entry permit with a sablefish endorsement or in the vessel registered to the permit shall document the extent of that ownership interest with NMFS via the Identification of Ownership Interest Form sent to the permit owner through the annual permit renewal process and whenever a change in permit owner, vessel owner, and/or vessel registration occurs as described at paragraph (b)(4)(iv) and (v) of this section. NMFS will not renew a sablefish-endorsed limited entry permit through the annual renewal process described at paragraph (b)(4)(i) of this section, or approve a change in permit owner, vessel owner, and/or vessel registration unless the Identification of Ownership Interest Form has been completed. Further, if NMFS discovers through review of the Identification of Ownership Interest Form that an individual person, partnership, or corporation owns or holds more than 3 permits and is not authorized to do so under paragraph (b)(3)(iv)(C)(2) of this section, the individual person, partnership or corporation will be notified and the permits owned or held by that individual person, partnership, or corporation will be void and reissued with the vessel status as ''unidentified'' until the permit owner owns and/or holds a quantity of permits appropriate to the restrictions and requirements described in paragraph (b)(3)(iv)(C)(2) of this section. If NMFS discovers through review of the Identification of Ownership Interest Form that a partnership or corporation has had a change in membership since November 1, 2000, as described in paragraph

(b)(3)(iv)(C)(3) of this section, the partnership or corporation will be notified, NMFS will void any existing permits, and reissue any permits owned and/or held by that partnership or corporation in ''unidentified'' status with respect to vessel registration until the partnership or corporation is able to register ownership of those permits to persons authorized under this section to own sablefish-endorsed limited entry permits.

* * * * *

(vii) *Endorsement and exemption restrictions.* ''A'' endorsements, gear endorsements, sablefish endorsements and sablefish tier assignments, and C/P endorsements may not be registered to another permit owner (i.e., change in permit ownership or ownership interest) or to another vessel (i.e., change in vessel registration) separately from the limited entry permit. At-sea processing exemptions, specified at paragraph (b)(6) of this section, are associated with the vessel and not with the limited entry permit and may not be registered to another permit owner or to another vessel without losing the exemption.

(4) *Limited entry permit actions—renewal, combination, stacking, change of permit owner or vessel owner, and change in vessel registration*

* * * * *

(i) * * *

(G) At the time of renewal, NMFS will notify owners of limited entry permits and vessel owners if vessel ownership information for a vessel registered to the permit is not current. NMFS will not renew a limited entry permit registered to a vessel for which vessel ownership information is not current.

* * * * *

(iv) *Changes in permit owner and/or vessel owner—*

(A) *General.* Change in permit owner and/or vessel owner applications must be submitted to NMFS with the appropriate documentation described at paragraphs (b)(4)(vii) and (viii) of this section. The permit owner may convey the limited entry permit to a different person. The new permit owner will not be authorized to use the permit until the change in permit owner has been registered with and approved by NMFS. NMFS will not approve a change in permit owner for a limited entry permit with a sablefish endorsement that does not meet the ownership requirements for such permit described at paragraph (b)(3)(iv)(C) of this section. NMFS will not approve a change in permit owner for a limited entry permit with an MS/CV endorsement or an MS permit that does not meet the ownership requirements for such permit described at § 660.150(g)(3), and § 660.150(f)(3), respectively. NMFS considers the following as a change in permit owner that would require registering with and approval by NMFS, including but not limited to: Selling the permit to another individual or entity; adding an individual or entity to the legal name on the permit; or removing an individual or entity from the legal name on the permit. A change in vessel owner includes any changes to the name(s) of any or all vessel owners, as registered with USCG or a state. The new owner(s) of a vessel registered to a limited entry permit must report any change in vessel ownership to NMFS within 30 calendar days after such change has been registered with the USCG or a state licensing agency.

(B) *Effective date.* The change in permit ownership or change in the vessel holding the permit will be effective on the day the change is approved by NMFS, unless there is a concurrent change in the vessel registered to the permit. Requirements for changing the vessel registered to the permit are described at paragraph (b)(4)(v) of this section.

(C) *Sablefish-endorsed permits.* If a permit owner submits an application to register a sablefish-endorsed limited entry permit to a new permit owner or vessel owner during the primary sablefish season described at § 660.231 (generally April 1 through October 31), the initial permit owner must certify on the application form the cumulative quantity, in round weight, of primary season sablefish landed against that permit as of the application signature date for the then current primary season. The new permit owner or vessel owner must sign the application form acknowledging the amount of landings to date given by the initial permit owner. This certified amount should match the total amount of primary season sablefish landings reported on state landing receipts. As required at § 660.12(b), any person landing sablefish must retain on board the vessel from which sablefish is landed, and provide to an authorized officer upon request, copies of any and all reports of sablefish landings from the primary season containing all data, and in the exact manner, required by the applicable state law throughout the primary sablefish season during which a landing occurred and for 15 days thereafter.

* * * * *

(v) * * *

(B) *Application.* Change in vessel registration applications must be submitted to NMFS with the appropriate documentation described at paragraphs (b)(4)(vii) and (viii) of this section. At a minimum, a permit owner seeking to change vessel registration of a limited entry permit shall submit to NMFS a signed application form and his/her current limited entry permit before the first day of the cumulative limit period in which they wish to fish. If a permit owner provides a signed application and current limited entry permit after the first day of a cumulative limit period, the permit will not be effective until the succeeding cumulative limit period. NMFS will not approve a change in vessel registration until it receives a complete application, the existing permit, a current copy of the USCG 1270, and other required documentation.

* * * * *

(D) *Sablefish-endorsed permits.* If a permit owner submits an application to register a sablefish-endorsed limited entry permit to a new vessel during the primary sablefish season described at § 660.231 (generally April 1 through October 31), the initial permit owner must certify on the application form the cumulative quantity, in round weight, of primary season sablefish landed against that permit as of the application signature date for the then current primary season. The new permit owner or vessel owner associated with the new vessel must sign the application form acknowledging the amount of landings to date given by the initial permit owner. This certified amount should match the total amount of primary season sablefish landings reported on state landing receipts. As required at § 660.12(b), any person landing sablefish must retain on board the vessel from which sablefish is landed, and provide to an authorized officer upon request, copies of any and all reports of sablefish landings from the primary season containing all data, and in the exact manner, required by the applicable state law throughout the primary sablefish season during which a landing occurred and for 15 days thereafter.

* * * * *

(vi) * * *

(B) *Limited entry fixed gear and trawl-endorsed permits (without MS/CV or C/P endorsements).* Limited entry fixed gear and trawl-endorsed permits (without MS/CV or C/P endorsements) may not be registered for use with a different vessel more than once per calendar year, except in cases of death of a vessel owner or if the vessel registered to the permit is totally lost as defined in § 660.11. The exception for death of a vessel owner applies for a

vessel owned by a partnership or a corporation if the person or persons with at least 50 percent of the ownership interest in the entity dies.

* * * * *

(vii) *Application and supplemental documentation.* Permit owners may request a change in vessel registration and/or change in permit owner or vessel owner by submitting a complete application form. In addition, a permit owner applying for a change in vessel registration and/or change in permit owner of a limited entry permit has the burden to submit evidence to prove that qualification requirements are met. If a change in vessel owner occurs, the new vessel owner has the burden to submit evidence to prove that qualification requirements are met. The following evidentiary standards apply:

(A) For a request to change a vessel registration and/or change a permit owner or vessel owner, the permit owner must provide NMFS with a current copy of the USCG Form 1270 for vessels of 5 net tons or greater, or a current copy of a state registration form for vessels under 5 net tons.

(B) For a request to change a vessel registration and/or change a permit owner or vessel owner for sablefish-endorsed permits with a tier assignment for which a corporation or partnership is listed as permit owner and/or vessel owner, an Identification of Ownership Interest Form must be completed and included with the application form.

(C) For a request to change a permit owner for an MS permit or for a request to change a vessel registration and/or change a permit owner or vessel owner for an MS/CV-endorsed limited entry trawl permit, an Identification of Ownership Interest Form must be completed and included with the application form.

* * * * *

(viii) *Application forms available.* Application forms for a change in vessel registration, permit owner, or vessel owner are available at: NMFS Northwest Region, Sustainable Fisheries Division, ATTN: Fisheries Permit Office, 7600 Sand Point Way, NE., Seattle, WA 98115; or *http://www.nwr.noaa.gov/fisheries/management/groundfish_permits/limited_entry_permits.html.* Contents of the application, and required supporting documentation, are also specified in the application form. Only complete applications will be processed.

* * * * *

(g) * * *

(1) *General.* For permit actions, including issuance, renewal, change in vessel registration and/or change in permit owner or vessel owner, and endorsement upgrade, the Assistant Regional Administrator for Sustainable Fisheries will make an IAD on the action. In cases where the applicant disagrees with the IAD, the applicant may appeal that decision. Final decisions on appeals of IADs regarding issuance, renewal, change in vessel registration and/or change in permit owner or vessel owner, and endorsement upgrade, will be made in writing by the Regional Administrator acting on behalf of the Secretary of Commerce and will state the reasons therefore. This section describes the procedures for appealing the IAD on permit actions made in this title under subparts C through G of part 660. Additional information regarding appeals of an IAD related to the trawl rationalization program is contained in the specific program sections under subpart D of part 660.

* * * * *

■ 5. In § 660.111, under the definition of ''Accumulation limits'', revise paragraph (1)(ii) for the definition for ''Vessel limits'' to read as follows:

§ 660.111 Trawl fishery—definitions.

* * * * *

(1) * * *

(ii) *Vessel limits* means the maximum amount of QP a vessel can hold, acquire, and/or use during a calendar year, and specify the maximum amount of QP that may be registered to a single vessel during the year (QP Vessel Limit) and, for some species, the maximum amount of unused QP registered to a vessel account at any one time (Unused QP Vessel Limit), as described at § 660.140(e)(4). Compliance with the QP vessel limit (annual limit) is calculated as all QPs transferred in minus all QPs transferred out of the vessel account.

* * * * *

■ 6. In § 660.112, add paragraphs (b)(1)(xvi) and (b)(1)(xvii), and revise paragraph (b)(2)(ii) to read as follows:

§ 660.112 Trawl fishery—prohibitions.

* * * * *

(b) * * *

(1) * * *

(xvi) Fail to establish a new registered vessel account in the name of the current vessel owner, following a change in ownership of a vessel, prior to fishing in the Shorebased IFQ Program with that vessel.

(xvii) Land groundfish taken and retained during an IFQ trip, from the vessel that harvested the fish, to a first receiver that does not hold a valid first receiver site license for the physical location where the IFQ landing occurred.

* * * * *

(2) * * *

(ii) Fail to sort fish received from a IFQ landing prior to first weighing after offloading as specified at § 660.130(d)(2) for the Shorebased IFQ Program, with the following exception. Vessels with a valid Shorebased IFQ Program declaration as specified at § 660.13(d)(5)(iv)(A) making an IFQ landing, may weigh catch on a bulk scale or automatic hopper scale before sorting as described at § 660.140(j)(2)(viii), for Pacific whiting taken with midwater trawl gear, and at § 660.140(j)(2)(ix)(A), for all other IFQ landings. For this exception, all catch in the landing other than the single predominant species must then be reweighed. The weight of a single predominant species is determined by deducting the weight of all other species from the total weight of the landing.

* * * * *

■ 7. In § 660.113, revise paragraphs (c)(3) and (d)(3) to read as follows:

§ 660.113 Trawl fishery—recordkeeping and reporting.

* * * * *

(c) * * *

(3) *Annual coop report.* The designated coop manager for the mothership coop must submit an annual report to NMFS and the Council by March 31 each year, before a coop permit is issued for that year. The annual coop report will contain information about the previous year's fishery, including:

(i) The mothership sector's annual allocation of Pacific whiting and the permitted mothership coop allocation;

(ii) The mothership coop's actual retained and discarded catch of Pacific whiting, salmon, Pacific halibut, rockfish, groundfish, and other species on a vessel-by-vessel basis;

(iii) A description of the method used by the mothership coop to monitor performance of coop vessels that participated in the fishery;

(iv) A description of any actions taken by the mothership coop in response to any vessels that exceed their allowed catch and bycatch; and

(v) Plans for the current year's mothership coop fishery, including the companies participating in the cooperative, the harvest agreement, and catch monitoring and reporting requirements.

* * * * *

(d) * * *

(3) *Annual coop report.* The designated coop manager for the C/P

coop must submit an annual report to NMFS and the Council by March 31 each year, before a coop permit is issued for that year. The annual coop report will contain information about the previous year's fishery, including:

(i) The C/P sector's annual allocation of Pacific whiting;

(ii) The C/P coop's actual retained and discarded catch of Pacific whiting, salmon, Pacific halibut, rockfish, groundfish, and other species on a vessel-by-vessel basis;

(iii) A description of the method used by the C/P coop to monitor performance of cooperative vessels that participated in the fishery;

(iv) A description of any actions taken by the C/P coop in response to any vessels that exceed their allowed catch and bycatch; and

(v) Plans for the current year's C/P coop fishery, including the companies participating in the cooperative, the harvest agreement, and catch monitoring and reporting requirements.

* * * * *

■ 8. In § 660.130, revise paragraphs (d)(2)(i), (d)(2)(ii) and (d)(3)(i) to read as follows:

§ 660.130 Trawl fishery—management measures.

* * * * *

(d) * * *

(2) * * *

(i) *First receivers.* Fish landed at IFQ first receivers (including shoreside processing facilities and buying stations that intend to transport catch for processing elsewhere) must be sorted, prior to first weighing after offloading from the vessel and prior to transport away from the point of landing, with the following exception. Vessels with a valid Shorebased IFQ Program declaration as specified at § 660.13(d)(5)(iv)(A) making an IFQ landing, may weigh catch on a bulk scale or automatic hopper scale before sorting as described at § 660.140(j)(2)(viii), for Pacific whiting taken with midwater trawl gear, and at § 660.140(j)(2)(ix)(A), for all other IFQ landings. For this exception, all catch in the landing other than the single predominant species must then be reweighed. The weight of a single predominant species is determined by deducting the weight of all other species from the total weight of landing.

(ii) *Catcher vessels.* All catch must be sorted to the species groups specified in paragraph (d)(1) of this section for vessels with limited entry permits, except those retaining all catch during a IFQ trip. The catch must not be discarded from the vessel and the vessel must not mix catch from hauls until the observer has sampled the catch. Prohibited species must be sorted according to the following species groups: Dungeness crab, Pacific halibut, Chinook salmon, other salmon. Non-groundfish species must be sorted as required by the state of landing.

* * * * *

(3) * * *

(i) Pacific whiting at-sea processing vessels may use an accurate in-line conveyor or hopper type scale to derive an accurate total catch weight prior to sorting. Immediately following weighing of the total catch, the catch must be sorted to the species groups specified in paragraph (d)(1) of this section and all incidental catch (groundfish and non-groundfish species) must be accurately accounted for and the weight of incidental catch deducted from the total catch weight to derive the weight of a single predominant species.

* * * * *

■ 9. In § 660.140,

■ a. Revise paragraph (b)(1)(iii);

■ b. Add paragraph (d)(2)(iii), revise paragraphs (d)(3)(i)(A) and (C), (d)(3)(ii)(B)(*2*) and (*3*)(*ii*), delete paragraph (d)(3)(ii)(B)(*3*)(*iii*), and revise paragraph (d)(4)(iii);

■ c. Revise paragraphs (e)(3)(iii)(B), (e)(4)(i), and (e)(5)(ii)(A);

■ d. Revise paragraphs (f)(2)(ii), (f)(3) introductory text, (f)(3)(i) and (ii),(f)(3)(iii)(A) and (B), add paragraph (f)(3)(iii)(C)(*12*), and revise paragraph (f)(3)(iii)(D);

■ e. Revise paragraphs (f)(5) and (f)(6), and

■ f. Revise paragraphs (j)(2)(viii) and (j)(2)(ix)(B), to read as follows:

§ 660.140 Shorebased IFQ Program.

* * * * *

(b) * * *

(1) * * *

(iii) All IFQ species/species group catch (landings and discards) must be covered by QP or IBQ pounds. Any deficit (negative balance in a vessel account) must be cured within 30 calendar days from the date the deficit from that trip is documented in the vessel account, unless the deficit is within the limits of the carryover provision at paragraph (e)(5) of this section, in which case the vessel account owner must declare out of the Shorebased IFQ Program, and must eliminate the deficit prior to re-entry into the fishery in the current year, or within 30 days after the issuance of QP or IBQ pounds for the following year.

* * * * *

(d) * * *

(2) * * *

(iii) *QS permit application process.* NMFS will accept a QS permit application from January 1 to November 30 of each calendar year. QS permit applications received between December 1 and December 31 will be processed by NMFS in the following calendar year. NMFS will issue only one QS permit to each unique person, as defined at § 660.11 subject to the eligibility requirements at § 660.140(d)(2)(i). Each applicant must submit a complete application. A complete application includes a QS permit application form, payment of required fees, complete documentation of QS permit ownership on the Trawl Identification of Ownership Interest Form as required under paragraph (d)(4)(iv) of this section, and a complete economic data collection form if required under § 660.114. NMFS may require additional documentation as it deems necessary to make a determination on the application. The QS permit application will be considered incomplete until the required information is submitted.

(A) *Initial administrative determination.* For all complete applications, NMFS will issue an IAD that either approves or disapproves the application. If approved, the QS permit serves as the IAD. If disapproved, the IAD will provide the reasons for this determination. If the applicant does not appeal the IAD within 30 calendar days, the IAD becomes the final decision of the Regional Administrator acting on behalf of the Secretary of Commerce.

(B) *Effective date.* The QS permit is effective on the date given on the permit and remains effective until the end of the calendar year.

(C) *Appeals.* If NMFS does not accept the QS permit application, the applicant may appeal the IAD consistent with the general permit appeals process defined at § 660.25(g).

(3) * * *

(i) * * *

(A) QS permits expire at the end of each calendar year, and must be renewed between October 1 and November 30 of each year in order to remain in effect the following year. A complete QS permit renewal package must be received by NMFS no later than November 30 to be accepted by NMFS. A QS permit owner may submit a paper renewal package after January 1 of the following year as described in paragraph (d)(3)(i)(C) of this section.

* * * * *

(C) A complete QS permit renewal package must be received by November 30 of each calendar year. If a complete QS permit renewal package is not received by November 30, NMFS will not renew the QS permit, the associated

QS account will not be activated in the following calendar year, and QS may not be transferred. NMFS will not issue QP or IBQ pounds associated with the non-renewed QS permit for that year. Any QP or IBQ pounds derived from the QS or IBQ in the inactive QS account will be distributed to the active QS accounts in proportion to the QS or IBQ for each IFQ species given on the renewed QS permit. If a QS permit is not renewed during the October 1 through November 30 renewal period, the QS permit owner may renew after January 1 in the following year by submission of a paper renewal application, or may renew the QS permit during the next October 1 through November 30 renewal period. For renewals submitted after January 1, QPs allocated as specified at paragraph (d)(1) of this section will not be allocated to the QS account in that year. The QS permit owner will be able to transfer QS percentages from the time the QS account is activated until November 30 of that calendar year.

* * * * *

(3) * * *

(ii) * * *

(B) * * *

(*2*) *Transfer of QS or IBQ between QS accounts.* Beginning January 1, 2014, QS permit owners may transfer QS (except for widow rockfish QS) or IBQ to another owner of a QS permit, subject to accumulation limits and approval by NMFS. The prohibition on transferability of widow rockfish QS is extended indefinitely pending final action on reallocation of widow rockfish QS, or a NMFS determination that no such reallocation will occur, except under U.S. court order or authorization and as approved by NMFS. QS or IBQ is transferred as a percent, divisible to one-thousandth of a percent (i.e., greater than or equal to 0.001%). QS or IBQ cannot be transferred to a vessel account. Owners of non-renewed QS permits may not transfer QS. QP in QS accounts cannot be transferred between QS accounts. NMFS will allocate QP based on the QS percentages as listed on a QS permit that was renewed during the previous October 1 through November 30 renewal period. QS transfers will be recorded in the QS account but will not become effective for purposes of allocating QPs until the following year. QS or IBQ may not be transferred between December 1 through December 31 each year. Any QS transaction that is pending as of December 1 will be administratively retracted. NMFS will allocate QP for the following year based on the QS percentages as of December 1 of each year.

* * * * *

(*3*) * * *

(*ii*) The QS account transfer function will be reactivated by NMFS from the date that QS accounts are credited with additional QP to allow QS permit owners to transfer QP to vessel accounts only for those IFQ species with additional QP.

(4) * * *

(iii) *Control.* Control means, but is not limited to, the following:

(A) The person has the right to direct, or does direct, in whole or in part, the business of the entity to which the QS or IBQ are registered, with the exception of those activities allowed under paragraphs C and G;

(B) The person has the right to limit the actions of or replace, or does limit the actions of or replace, the chief executive officer, a majority of the board of directors, any general partner, or any person serving in a management capacity of the entity to which the QS or IBQ are registered, with the exception of those activities allowed under paragraphs C and G;

(C) The person, excluding banks and other financial institutions that rely on QS or IBQ as collateral for loans as described under paragraph (G) below, has the right to direct, or does direct, and/or the right to prevent or delay, or does prevent or delay, the transfer of QS or IBQ, or the resulting QP or IBQ pounds;

(D) The person, through loan covenants or any other means, has the right to restrict, or does restrict, and/or has a controlling influence over the day to day business activities or management policies of the entity to which the QS or IBQ are registered, with the exception of those activities allowed under paragraphs C and G;

(E) The person, has the right to restrict, or does restrict, any activity related to QS or IBQ or QP or IBQ pounds, including, but not limited to, use of QS or IBQ, or the resulting QP or IBQ pounds, or disposition of fish harvested under the resulting QP or IBQ pounds, with the exception of those activities allowed under paragraphs C and G;

(F) The person has the right to control, or does control, the management of, or to be a controlling factor in, the entity to which the QS or IBQ, or the resulting QP or IBQ pounds, are registered, with the exception of those activities allowed under paragraphs C and G;

(G) The person, excluding banks and other financial institutions that rely on QS or IBQ as collateral for loans, has the right to cause or prevent, or does cause or prevent, the sale, lease or other disposition of QS or IBQ, or the resulting QP or IBQ pounds; and

(*1*) To qualify for this exception, a bank or other financial institution must be regularly or primarily engaged in the business of lending and not engaged in or controlled by entities whose primary business is the harvesting, processing, or distribution of fish or fish products.

(*2*) Any state or federally chartered bank or financial institution that meets the requirement of paragraph (*1*) does not need to submit additional information to NMFS.

(*3*) Any entity that is not a state or federally chartered bank or financial institution, must submit a letter requesting the exception and disclose the identity and interest share of any shareholder with a 2% or more ownership interest in the lender through submission of the Trawl Identification of Ownership Interest Form (see § 660.140(d)(4)(iv)). The lender must make subsequent annual submissions of the letter and Trawl Identification of Ownership Interest Form to maintain the exception. Letters requesting the exception and complete Trawl Identification of Ownership Interest Forms may be submitted to NMFS, Northwest Region, Permits Office, ATTN: Fisheries Permit Office, Bldg. 1, 7600 Sand Point Way NE., Seattle, WA 98115. NMFS will only accept complete applications.

(H) The person has the ability through any means whatsoever to control or have a controlling influence over the entity to which QS or IBQ is registered, with the exception of those activities allowed under paragraphs C and G.

* * * * *

(e) * * *

(3) * * *

(iii) * * *

(B) *Transfer procedures.* QP or IBQ pound transfers from one vessel account to another vessel account must be accomplished via the online vessel account. To make a transfer, a vessel account owner must initiate a transfer request by logging onto the online vessel account. Following the instructions provided on the Web site, the vessel account owner must enter pertinent information regarding the transfer request including, but not limited to: IFQ species, amount of QP or IBQ pounds to be transferred for each IFQ species (in whole pound increments); name and any other identifier of the eligible transferee (e.g., USCG documentation number or state registration number, as applicable) of

the eligible vessel account receiving the transfer; and the value of the transferred QP or IBQ pounds. The online system will verify whether all information has been entered and whether the transfer complies with vessel limits, as applicable. If the information is not accepted, an electronic message will record as much in the transferor's vessel account explaining the reason(s). If the information is accepted, the online system will record the pending transfer in both the transferor's and the transferee's vessel accounts. The transferee must approve the transfer by electronic signature. If the transferee accepts the transfer, the online system will record the transfer and confirm the transaction in both accounts through a transaction confirmation notice. Once the transferee accepts the transaction, the transaction is final and permanent. QP or IBQ pounds may be transferred between vessel accounts at any time during January 1 through December 31 each year unless otherwise notified by NMFS.

* * * * *

(4) * * *

(i) *Vessel limits.* For each IFQ species or species group specified in this paragraph, vessel accounts may not have QP or IBQ pounds in excess of the QP vessel limit (annual limit) in any year, and, for species covered by unused QP vessel limits (daily limit), may not have QP or IBQ pounds in excess of the unused QP vessel limit at any time. The QP vessel limit (annual limit) is calculated as all QPs transferred in minus all QPs transferred out of the vessel account. The unused QP vessel limits (daily limit) is calculated as unused available QPs plus any pending outgoing transfer of QPs.

* * * * *

(5) * * *

(ii) * * *

(A) The vessel account owner declares out of the Shorebased IFQ Program for the year in which the deficit occurred. The vessel account owner must submit a signed, dated, and notarized letter to OLE, declaring out of the Shorebased IFQ Program for the remainder of the year and invoking the carryover provision to cover the deficit. Signed, dated, and notarized letters may be submitted to NMFS, Northwest Region, Office of Law Enforcement, ATTN VMS, Bldg. 1, 7600 Sand Point Way NE., Seattle, WA 98115. If the vessel account owner covers the deficit later within the same calendar year, the vessel may re-enter the Shorebased IFQ Program. If the deficit occurs less than 30 days before the end of the calendar year, exiting out of the Shorebased IFQ Program for the remainder of the year is not required.

* * * * *

(f) * * *

(2) * * *

(ii) An IFQ first receiver must have a separate first receiver site license for each unique physical location where the IFQ first receiver will receive, purchase or take custody, control, or take possession of an IFQ landing from a vessel.

* * * * *

(3) *Application process.* Persons interested in being licensed as an IFQ first receiver for a specific physical location must submit a complete application for a first receiver site license to NMFS, Northwest Region, ATTN: Fisheries Permit Office, Bldg. 1, 7600 Sand Point Way NE., Seattle, WA 98115. NMFS will only consider complete applications for approval. A complete application includes:

(i) *State license.* The license owner must provide a copy of a valid license issued by the state in which they operate that allows the person to receive fish from a catcher vessel.

(ii) *Application form.* A completed IFQ first receiver application form provided by NMFS, signed and dated by an authorized representative of the first receiver. To be considered complete, the form must also be notarized.

* * * * *

(iii) * * *

(A) *Catch monitoring plan review process.* NMFS will accept a catch monitoring plan if it includes all the required elements specified in paragraph (f)(3)(iii)(C) of this section and conforms with the actual operations and layout at the site. A site inspection is required for new first receiver site licenses. For re-registration of an existing first receiver site license, the site must be inspected at least once every three years or more frequently, as deemed necessary by NMFS, or by a NMFS designated representative. If NMFS does not accept a catch monitoring plan for any reason, a new or revised catch monitoring plan may be required of the first receiver.

(B) *Arranging a site inspection.* After receiving a complete application for a first receiver site license, if a site inspection is required, NMFS will contact the applicant to schedule a site inspection. A complete application for a first receiver site license must include the proposed catch monitoring plan. NMFS may request a representative of the first receiver to be at the site at the time of inspection. If the requested representative of the first receiver is not made available for the inspection, the site inspection may be postponed until the requested representative of the first receiver is made available.

* * * * *

(C) * * *

(*12*) *Applicant contact.* Print the name of the first receiver, physical location of the first receiver, name and phone number of the applicant, and the date of the application. The applicant must sign the catch monitoring plan.

* * * * *

(D) *Catch monitoring plan acceptance period and changes.* NMFS will accept a catch monitoring plan if it includes the required elements specified in paragraph (f)(3)(iii)(C) of this section and conforms with the actual operations and layout at the site. For the first receiver site license to remain in effect, the owner or manager must notify NMFS in writing of any and all changes made in IFQ first receiver operations or layout that do not conform to the catch monitoring plan.

* * * * *

(5) *Effective dates.* The first receiver site license is valid from the effective date identified on the license until June 30, or until the state license required by paragraph (f)(2)(i) of this section is no longer effective, whichever occurs first. A first receiver site license may not be valid for more than 365 days.

(6) *Re-registration of FRSL in subsequent years.* Existing first receiver site license holders must reapply annually by following the application process specified in paragraph (f)(3) of this section. If the existing license holder fails to reapply, the first receiver site license will expire as specified in paragraph (f)(5) of this section. For existing first receiver site license holders to continue to receive IFQ landings without a lapse in the effectiveness of their first receiver site license, the following re-registration deadlines apply:

(i) NMFS will mail a first receiver site license application to existing license holders on or about February 1 each year.

(ii) Applicants who want to have their new license effective for July 1 must submit their complete re-registration application to NMFS by April 15. For those first receiver site license holders who do not submit a complete re-registration application by April 15, NMFS may not be able to issue the new license by July 1 of that calendar year, and will issue the new license as soon as practicable.

* * * * *

(j) * * *

(2) * * *

(viii) *Pacific whiting.* For Pacific Whiting taken with midwater trawl gear, IFQ first receivers may use an in-line conveyor or hopper type scale to derive an accurate total catch weight prior to sorting. Immediately following weighing of the total catch and prior to processing or transport away from the point of landing, the catch must be sorted to the species groups specified at § 660.130(d) and all incidental catch (groundfish and non groundfish species) must be accurately weighed and the weight of incidental catch deducted from the total catch weight to derive the weight of a single predominant species.

(ix) * * *

(B) An in-line conveyor or automatic hopper scale may be used to weigh the single predominant species after catch has been sorted. Other species must be weighed in a manner that facilitates tracking of the weights of those species.

* * * * *

■ 10. In § 660.150, revise paragraphs (c)(7)(i), (d)(1)(iii)(A)(*1*)(*i*), and (g)(2)(iv)(D) to read as follows:

§ 660.150 Mothership (MS) Coop Program.

* * * * *

(c) * * *

(7) * * *

(i) *Processor obligation.* Through the annual MS/CV-endorsed limited entry permit renewal process, the MS/CV-endorsed permit owner must identify to NMFS to which MS permit the MS/CV permit owner intends to obligate the catch history assignment associated with that permit if they are participating in the MS coop fishery. Only one MS permit may be designated for each MS/CV endorsement and associated catch history assignment.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(A) * * *

(*1*) * * *

(*i*) A list of all vessels and permit owners participating in the coop and their share of the allocated catch history assignments which must match the amount distributed to individual permit owners by NMFS.

* * * * *

(g) * * *

(2) * * *

(iv) * * *

(D) A limited entry trawl permit owner with multiple MS/CV-endorsements and associated CHA on a single permit may assign each distinct MS/CV endorsement and catch history assignment separately to coop(s) or the non-coop fishery. In such cases, as part of the coop permit application process, specified at paragraph (d)(1)(iii) of this section, the permit owner must specify on the coop permit application form which MS/CV endorsement and associated CHA is specifically registered to a particular coop.

* * * * *

■ 11. In § 660.213, revise paragraph (d)(2) to read as follows:

§ 660.213 Fixed gear fishery—recordkeeping and reporting.

* * * * *

(d) * * *

(2) For participants in the sablefish primary season, the cumulative limit period to which this requirement applies is April 1 through October 31 or, for an individual vessel owner, when the tier limit for the permit(s) registered to the vessel has been reached, whichever is earlier.

■ 12. In § 660.216, revise paragraph (a)(1) to read as follows:

§ 660.216 Fixed gear fishery—observer requirements.

(a) * * *

(1) When NMFS notifies the vessel owner, operator, or the manager of a catcher vessel, specified at § 660.16(c), of any requirement to carry an observer, the catcher vessel may not be used to fish for groundfish without carrying an observer.

* * * * *

■ 13. In § 660.231, revise paragraph (b)(1) to read as follows:

§ 660.231 Limited entry fixed gear sablefish primary fishery.

* * * * *

(b) * * *

(1) *Season dates.* North of 36° N. lat., the sablefish primary season for the limited entry, fixed gear, sablefish-endorsed vessels begins at 12 noon local time on April 1 and closes at 12 noon local time on October 31, or closes for an individual vessel owner when the tier limit for the permit(s) registered to the vessel has been reached, whichever is earlier, unless otherwise announced by the Regional Administrator through the routine management measures process described at § 660.60(c).

* * * * *

■ 14. In § 660.316, revise paragraph (a)(1) to read as follows:

§ 660.316 Open access fishery—observer requirements.

(a) * * *

(1) When NMFS notifies the vessel owner, operator, or the vessel manager of a catcher vessel, specified at § 660.16(c), of any requirement to carry an observer, the catcher vessel may not be used to fish for groundfish without carrying an observer.

* * * * *

[FR Doc. 2013–17162 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 78, No. 139
Friday, July 19, 2013

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Marine Recreational Information Program Fishing Effort Survey.

OMB Control Number: 0648–0652.

Form Number(s): NA.

Type of Request: Regular submission (revision of a current information collection).

Number of Respondents: 153,000.

Average Hours per Response: 10 minutes.

Burden Hours: 25,500.

Needs and Uses: This request is for revision of a current information collection. The title will be changed from ''Marine Recreational Information Program'' to ''Marine Recreational Information Program Fishing Effort Survey''.

Marine recreational anglers are surveyed to collect catch and effort data, fish biology data, and angler socioeconomic characteristics. These data are required to carry out provisions of the Magnuson-Stevens Fishery Conservation and Management Act (MSA, 16 U.S.C. 1801 et seq.), as amended, regarding conservation and management of fishery resources.

Marine recreational fishing effort data have traditionally been collected through the Coastal Household Telephone Survey, a random-digit-dial telephone survey of coastal county residences. Amendments to the MSA require the development of an improved data collection program for recreational fisheries. To meet these requirements, the National Oceanic and Atmospheric Administration's (NOAA) Fisheries has designed and tested new approaches for sampling and surveying recreational anglers. Revision: A mail survey that samples from residential address frames and collects information on the number of marine recreational anglers and the number of recreational fishing trips is currently being tested in MA, NY, NC and FL. The survey will be expanded to all Atlantic and Gulf coast states (except TX), HI and Puerto Rico.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov.*

Dated: July 15, 2013.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2013–17299 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Southwest Region Permit Family of Forms.

OMB Control Number: 0648–0204.

Form Number(s): NA.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 1,761.

Average Hours per Response: Highly Migratory Species (HMS) permit renewals, 6 minutes; Coastal Pelagic Species (CPS) permit renewals, 15 minutes; CPS permit appeals, 2 hours; CPS transfers, 30 minutes; experimental fishing permits (EFPs), 1 hour.

Burden Hours: 135.

Needs and Uses: This request is for r extension of a current information collection. Under the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 et *seq.,* permits are required for persons to participate in Federally-managed fisheries off the West Coast. There are three types of permits: basic fishery permits for HMS, limited entry permits for CPS and EFPs. Appeals and certain waiver requests may also be submitted. Transfer applications may also be required.

The permit application forms provide basic information about permit holders and the vessels and gear being used. This information is important for understanding the nature of the fisheries and provides a link to participants. It also aids in enforcement of regulations.

Affected Public: Business or other for-profit organizations.

Frequency: Annually, biannually and on occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov.*

Dated: July 15, 2013.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2013–17274 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–23–2013]

Foreign-Trade Zone 93—Raleigh-Durham, North Carolina, Authorization of Production Activity, Southern Lithoplate, Inc. (Aluminum Printing Plates), Youngsville, North Carolina

On March 18, 2013, the Triangle J Council of Governments, grantee of FTZ 93, submitted a notification of proposed production activity to the Foreign-Trade Zones (FTZ) Board on behalf of Southern Lithoplate, Inc., within Site 5 of FTZ 93, in Youngsville, North Carolina.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (78 FR 17635, 3–22–2013). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the Board's regulations, including Section 400.14.

Dated: July 16, 2013.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2013–17388 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Proposed Information Collection; Comment Request; Implementation of Tariff Rate Quota Established Under Title V of the Trade and Development Act of 2000 for Imports of Certain Worsted Wool Fabric

AGENCY: International Trade Administration (ITA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before September 17, 2013.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Laurie Mease, Office of Textiles and Apparel, Telephone: 202–482–3400, Fax: 202–482–2331, Email: *Laurie.Mease@trade.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Title V of the Trade and Development Act of 2000 (''the Act'') as amended by the Trade Act of 2002, the Miscellaneous Trade Act of 2004, the Pension Protection Act of 2006, and the Emergency Economic Stabilization Act of 2008, contains several provisions to assist the wool products industries. These include the establishment of tariff rate quotas (''TRQ'') for a limited quantity of worsted wool fabrics. The Act requires the President to fairly allocate the TRQ to persons who cut and sew men's and boys' worsted wool suits and suit-like jackets and trousers in the United States, and who apply for an allocation based on the amount of suits they produce in the prior year. The Act specifies factors to be addressed in considering such requests. On December 1, 2000, the President issued Proclamation 7383 that, among other things, delegates authority to the Secretary of Commerce to allocate the TRQ and to issue regulations to implement these provisions. On January 22, 2001, the Department of Commerce published regulations establishing procedures for allocation of the tariff rate quotas (66 FR 6459, 15 CFR 335). The interim regulations were adopted, without change, as a final rule published on October 24, 2005 (70 FR 61363).

The TRQ was originally effective for goods entered or withdrawn from warehouse for consumption, on or after January 1, 2001, and was to remain in force through 2003. On August 6, 2002, President Bush signed into law the Trade Act of 2002, which includes several amendments to Title V of the Act including the extension of the program through 2005. On December 3, 2004, the Act was further amended pursuant to the Miscellaneous Trade Act of 2004, Public Law 108–429, by increasing the TRQ for worsted wool fabric with average fiber diameters greater than 18.5 microns, HTS 9902.51.11, to an annual total level of 5.5 million square meters, and extending it through 2007, and increasing the TRQ for average fiber diameters of 18.5 microns or less, HTS 9902.51.15 (previously 9902.51.12), to an annual total level of 5 million square meters and extending it through 2006. On August 17, 2006, the Act was further amended pursuant to the Pension Protection Act of 2006, Public Law 109–280, which extended both TRQs, 9902.51.11 and 9902.51.15, through 2009. The Emergency Economic Stabilization Act of 2008 extended the TRQs through 2014.

The Department must collect certain information in order to fairly allocate the TRQ to eligible persons. In order to be eligible for an allocation, an applicant must submit an application. An applicant must provide the following information in the format set forth in the application form provided by the Department:

(1) Identification. Applicant's name, address, telephone number, email address, and federal tax identification number; name of person submitting the application, and title, or capacity in which the person is acting for the applicant.

(2) Production Information. Name and address of each plant or location where Worsted Wool Suits, Worsted Wool Suit-Type Jackets, and Worsted Wool Trousers were cut and sewn by the applicant and the name and address of all plants or locations that cut and sewed such products on behalf of the applicant. Production data, including the following: the quantity and value of the Worsted Wool Suits, Worsted Wool Suit-Type Jackets, and Worsted Wool Trousers cut and sewn in the United States by applicant, or on behalf of applicant, from fabric owned by applicant. This data must indicate actual production (not estimates) of Worsted Wool Suits, Worsted Wool Suit-Type Jackets and Worsted Wool Trousers containing at least 85 percent worsted wool fabric by weight with an average diameter of 18.5 microns or less. This data must also indicate actual production (not estimates) of Worsted Wool Suits, Worsted Wool Suit-Type Jackets and Worsted Wool Trousers containing at least 85 percent worsted wool fabric by weight with average diameter greater than 18.5 microns. Production data must be provided for the first six months of the year of the application. This data will be annualized for the purpose of making Tariff Rate Quota allocation.

(3) Worsted Wool Fabric. Data indicating the quantity and value of the Worsted Wool Fabric used in reported production.

(4) Certification. A statement by the applicant, or on behalf of the applicant, by an employee, officer or agent, with

personal knowledge of the matters set out in the application, certifying that the information contained therein is complete and accurate, signed and sworn before a Notary Public, and acknowledging that false representations to a federal agency may result in criminal penalties under federal law.

Not later than September 30 of each Tariff Rate Quota Year, a licensee that will not import the full quantity granted in a license during the Tariff Rate Quota Year shall surrender the allocation that will not be used to the Department for purposes of reallocation. The surrender shall be final, and shall apply only to that Tariff Rate Quota Year.

Revision: Forms for surrender and reallocation have been developed in order to create a standardized method of reporting such information. The information collected on the surrender and reallocation application is utilized to determine the eligibility of applicants for additional quota and the amount of additional quota they shall receive. The information includes:

(1) Identification. Licensee's name and the license control number. (2) The amount surrendered and/or the amount requested for reallocation.

II. Method of Collection

The information collection forms will be provided via the Internet and by mail to requesting firms.

III. Data

OMB Control Number: 0625–0240.

Form Number(s): ITA–4139, ITA–4140P.

Type of Review: Regular submission (revision to a currently approved information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 20.

Estimated Time Per Response: 3 hours.

Estimated Total Annual Burden Hours: 160.

Estimated Total Annual Cost to Public: $450.

IV. Request for Comments

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and costs) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 15, 2013.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2013–17301 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–920]

Lightweight Thermal Paper From the People's Republic of China: Rescission of Antidumping Duty Review; 2011–2012

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* July 19, 2013.

FOR FURTHER INFORMATION CONTACT: Eve Wang or Eugene Degnan, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at (202) 482–6231 or (202) 482–0414, respectively.

SUMMARY: The Department of Commerce (''Department'') is rescinding the 2011–2012 antidumping duty administrative review on lightweight thermal paper from the People's Republic of China (''PRC'') because Appleton Papers Inc. (''Petitioner''), timely withdrew its request for review.

SUPPLEMENTARY INFORMATION:

Background

On November 5, 2012, the Department published a notice of opportunity to request an administrative review of the antidumping duty order on lightweight thermal paper from the PRC.[1] The period of review (''POR'') is November 1, 2011, through October 31, 2012. On November 30, 2012, the Department received a timely request from Petitioner to conduct an administrative review of Shanghai Hanhong Paper Co., Ltd. and Hanhong International Limited; Guangdong Guanhao High-Tech Co., Ltd.; Henan Province Jianghe Paper Co., Ltd., Jianghe Paper Co., Ltd., and JHT Paper; New Pride Co., Ltd.; and Shenzhen Taizhou Industrial Development Co., Ltd. In this case, there were no other requests for an administrative review by any other party. Pursuant to this request, the Department initiated an administrative review of the antidumping duty order on lightweight thermal paper from the PRC for the POR.[2] On April 1, 2013, Petitioner withdrew its request for review for all of the aforementioned parties for which it had made a review request.

Scope of the Order

The merchandise covered by this review includes certain lightweight thermal paper, which is thermal paper with a basis weight of 70 grams per square meter (g/m^2) (with a tolerance of $\pm$ 4.0 g/m^2) or less; irrespective of dimensions;[3] with or without a base coat[4] on one or both sides; with thermal active coating(s)[5] on one or both sides that is a mixture of the dye and the developer that react and form an image when heat is applied; with or without a top coat;[6] and without an adhesive backing. Certain lightweight thermal paper is typically (but not exclusively) used in point-of-sale applications such as ATM receipts, credit card receipts, gas pump receipts, and retail store receipts. The merchandise subject to this review may be classified in the Harmonized Tariff Schedule of the United States (''HTSUS'') under subheadings 3703.10.60, 4811.59.20, 4811.90.8040, 4811.90.9090, 4820.10.20, 4823.40.00, 4811.90.8030, 4811.90.8050, 4811.90.9030, and

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 77 FR 66437 (November 5, 2012).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 77 FR 77017 (December 31, 2012).

[3] Lightweight thermal paper is typically produced in jumbo rolls that are slit to the specifications of the converting equipment and then converted into finished slit rolls. Both jumbo and converted rolls (as well as lightweight thermal paper in any other form, presentation, or dimension) are covered by the scope of these orders.

[4] A base coat, when applied, is typically made of clay and/or latex and like materials and is intended to cover the rough surface of the paper substrate and to provide insulating value.

[5] A thermal active coating is typically made of sensitizer, dye, and co-reactant.

[6] A top coat, when applied, is typically made of polyvinyl acetone, polyvinyl alcohol, and/or like materials and is intended to provide environmental protection, an improved surface for press printing, and/or wear protection for the thermal print head.

Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party that requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. In this case, Petitioner timely withdrew its request for a review, and no other interested party requested a review of the aforementioned parties. Therefore, the Department is rescinding the administrative review of the antidumping duty order on lightweight thermal paper from the PRC covering the period November 1, 2011, through October 31, 2012, in its entirety, in accordance with 19 CFR 351.213(d)(1).

Assessment

The Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries of lightweight thermal paper from the PRC during the POR at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR.

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO, in accordance with 19 CFR 351.305 and as explained in the APO itself. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is in accordance with section 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: July 15, 2013.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2013–17386 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–DS–P

4811.90.8020 (for gift wrap, a non-subject product) and 4811.90.8040 (for ''other'' including lightweight thermal paper). HTSUS subheading 4811.90.9000 was a classification for lightweight thermal paper until July 1, 2005. Effective that date, subheading 4811.90.9000 was replaced with 4811.90.9010 (for tissue paper, a non-subject product) and 4811.90.9090 (for ''other,'' including lightweight thermal paper).

[8] As of January 1, 2009, the International Trade Commission deleted HTSUS subheadings 4811.90.8040 and 4811.90.9090 and added HTSUS subheadings 4811.90.8030, 4811.90.8050, 4811.90.9030, and 4811.90.9050 to the HTSUS (2009). *See* HTSUS (2009), available at <*ww.usitc.gov*>. These HTSUS subheadings were added to the scope of the order in lightweight thermal paper's underlying investigation.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–985]

Xanthan Gum From the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the Department of Commerce (the ''Department'') and the International Trade Commission (''ITC''), the Department is issuing an antidumping duty order on xanthan gum from the People's Republic of China (''PRC''). In addition, the Department is amending its final determination to correct a ministerial error.

DATES: *Effective Date:* July 19, 2013.

FOR FURTHER INFORMATION CONTACT: Brandon Farlander or Erin Kearney, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0182 or (202) 482–0167, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 4, 2013, the Department published the final determination of sales at less than fair value in the antidumping duty investigation of xanthan gum from the PRC.[1] On July 12, 2013, the ITC notified the Department of its final determination pursuant to section 735(b)(1)(A)(ii) of the Tariff Act of 1930, as amended (''the Act''), that an industry in the United States is threatened with material injury by reason of imports of xanthan gum from the PRC.[2]

Scope of the Order

The scope of this order covers dry xanthan gum, whether or not coated or blended with other products. Further, xanthan gum is included in this order regardless of physical form, including, but not limited to, solutions, slurries, dry powders of any particle size, or unground fiber.

Xanthan gum that has been blended with other product(s) is included in this scope when the resulting mix contains 15 percent or more of xanthan gum by dry weight. Other products with which xanthan gum may be blended include, but are not limited to, sugars, minerals, and salts.

Xanthan gum is a polysaccharide produced by aerobic fermentation of *Xanthomonas campestris.* The chemical structure of the repeating pentasaccharide monomer unit consists of a backbone of two P–1,4-D-Glucose monosaccharide units, the second with a trisaccharide side chain consisting of P-D-Mannose-(1,4)- P-DGlucuronic acid-(1,2)-a-D-Mannose monosaccharide units. The terminal mannose may be pyruvylated and the internal mannose unit may be acetylated.

Merchandise covered by the scope of this order is classified in the Harmonized Tariff Schedule (''HTS'') of the United States at subheading 3913.90.20. This tariff classification is provided for convenience and customs purposes; however, the written description of the scope is dispositive.

Amendment to the Final Determination

On June 4, 2013, the Department published its affirmative final determination in this proceeding.[3] In accordance with 19 CFR 351.224(b), the Department disclosed to interested parties the details of its calculations for the final determination on May 30, 2013. On June 4, 2013, CP Kelco U.S. (''Petitioner''), petitioner in this investigation, and Neimenggu Fufeng Biotechnologies Co., Ltd. (aka Inner

[1] *See Xanthan Gum From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 78 FR 33351 (June 4, 2013) (''*Final Determination*'').

[2] *See Xanthan Gum from Austria and China,* USITC Publication 4411, Investigation Nos. 731–TA–1202–1203 (Final) (July 2013).

[3] *See Final Determination.*

Mongolia Fufeng Biotechnologies Co., Ltd.) (''Fufeng'') and Deosen Biochemical (''Deosen''), respondents in this investigation, timely submitted ministerial error allegations and requested, pursuant to 19 CFR 351.224, that the Department correct the alleged ministerial errors. On June 10, 2013, Petitioner submitted rebuttal comments to Deosen's ministerial error allegations, and Fufeng submitted rebuttal comments to Petitioner's ministerial error allegations. On June 11, 2013, the Department rejected Fufeng's rebuttal comments and allowed Fufeng to re-submit its rebuttal comments, which Fufeng did on June 12, 2013.

After analyzing all interested party comments and rebuttals, we have determined that, in accordance with section 735(e) of the Act and 19 CFR 351.224(e), a ministerial error was made with respect to the treatment of the coal ash by-product in Fufeng's margin calculation.[4]

In the *Final Determination,* we determined that a number of companies, in addition to the mandatory respondents, qualified for a separate rate.[5] Since the weighted-average dumping margin for the separate rate respondents is based on the average of the weighted-average dumping margins for the mandatory respondents, and the weighted-average dumping margin for Fufeng changed as a result of the aforementioned ministerial error, we have revised the calculation of the dumping margin for the separate rate respondents in the amended final determination. The amended dumping margins are provided, below.

Antidumping Duty Order

In accordance with section 735(d) of the Act, the ITC has notified the Department of its final determination in this investigation, in which it found that an industry in the United States is threatened with material injury within the meaning of section 735(b)(1)(A)(ii) of the Act. Therefore, in accordance with section 735(c)(2) of the Act, we are publishing this antidumping duty order. In accordance with section 736(a)(1) of the Act, the Department will direct U.S. Customs and Border Protection (''CBP'') to assess, upon further instruction by the Department, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, for all relevant entries of xanthan gum from the PRC.

Pursuant to section 736(b)(2) of the Act, duties shall be assessed on subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the ITC's notice of final determination if that determination is based on the threat of material injury, other than threat of material injury described in section 736(b)(1) of the Act.[6] In addition, section 736(b)(2) of the Act requires CBP to release any bond or other security, and refund any cash deposit made of estimated antidumping duties posted since the Department's preliminary antidumping duty determination.[7]

Suspension of Liquidation

Because the ITC's final determination is based on the threat of material injury and is not accompanied by a finding that injury would have resulted but for the imposition of suspension of liquidation of entries since the Department's preliminary determination, section 736(b)(2) of the Act is applicable. Therefore, the Department will instruct CBP to terminate the suspension of liquidation for entries of xanthan gum from the PRC entered, or withdrawn from warehouse, for consumption prior to the publication of the ITC's final determination and refund any cash deposits of estimated antidumping duties made between the publication of the Department's preliminary determination on January 10, 2013, and the publication of the ITC's final determination. Furthermore, we will instruct CBP to continue to suspend liquidation on all unliquidated entries of xanthan gum from the PRC entered, or withdrawn from warehouse, for consumption on or after the date of publication of the ITC's notice of final determination of threat of material injury in the **Federal Register**.

Effective on the date of publication of the ITC's notice of final determination in the **Federal Register**, CBP will require, pursuant to section 736(a)(3) of the Act, at the same time as importers would normally deposit estimated duties on this subject merchandise, a cash deposit equal to the weighted-average dumping margins listed below.[8] The rate for the PRC-wide entity applies to all exporter and producer combinations not specifically listed.

Amended Final Determination of Antidumping Investigation

The weighted-average dumping margins are as follows:

Exporter	Producer	Weighted-average dumping margin (percent)
Neimenggu Fufeng Biotechnologies Co., Ltd (aka Inner Mongolia Fufeng Biotechnologies Co., Ltd.)/Shandong Fufeng Fermentation Co., Ltd.	Neimenggu Fufeng Biotechnologies Co., Ltd. (aka Inner Mongolia Fufeng Biotechnologies Co., Ltd.)/Shandong Fufeng Fermentation Co., Ltd.	12.90
Deosen Biochemical Ltd	Deosen Biochemical Ltd./Deosen Biochemical (Ordos) Ltd	128.32
A.H.A. International Co., Ltd	Shandong Fufeng Fermentation Co., Ltd	70.61
A.H.A. International Co., Ltd	Deosen Biochemical Ltd	70.61
CP Kelco (Shandong) Biological Company Limited	CP Kelco (Shandong) Biological Company Limited	70.61
Hebei Xinhe Biochemical Co. Ltd	Hebei Xinhe Biochemical Co. Ltd	70.61
Shanghai Smart Chemicals Co. Ltd	Deosen Biochemical Ltd	70.61
PRC-Wide Entity*		154.07

*The PRC-wide entity includes Shandong Yi Lian Cosmetics Co., Ltd., Shanghai Echem Fine Chemicals Co., Ltd., Sinotrans Xiamen Logistics Co., Ltd., and Zibo Cargill HuangHelong Bioengineering Co., Ltd

[4] For a detailed discussion of the alleged ministerial errors, as well as the Department's analysis, *see* Memorandum to Paul Piquado, Assistant Secretary for Import Administration, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, regarding, ''Final Determination of Antidumping Duty Investigation of Xanthan Gum from the People's Republic of China: Allegation of Ministerial Errors,'' dated June 28, 2013.

[5] *See Final Determination,* 78 FR at 33353.

[6] Section 736(b)(1) of the Act states that ''{i}f the {ITC}, in its final determination under section 735(b), finds material injury or threat of material injury which, but for the suspension of liquidation under section 733(d)(2) would have led to a finding of material injury, then entries of the subject merchandise, the liquidation of which has been suspended under section 733(d)(2), shall be subject to the imposition of antidumping duties under section 731.''

[7] *See Xanthan Gum from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 77 FR 2252 (January 10, 2013) (''*Preliminary Determination*'').

[8] *See* section 736(a)(3) of the Act.

This notice constitutes the antidumping duty order with respect to xanthan gum from the PRC pursuant to section 736(a) of the Act. Interested parties may contact the Department's Central Records Unit, Room 7043 of the main Commerce building, for copies of an updated list of antidumping duty orders currently in effect.

This order and amended final determination are published in accordance with sections 735(e), 736(a) and 777(i) of the Act, and 19 CFR 351.211 and 351.224(e).

Dated: July 15, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2013–17380 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No. 120921480–2480–01]

Announcing Approval of Federal Information Processing Standard 186–4, Digital Signature Standard

AGENCY: National Institute of Standards and Technology (NIST), Department of Commerce.

ACTION: Notice.

SUMMARY: This notice announces the Secretary of Commerce's approval of Federal Information Processing Standard (FIPS) 186–4, Digital Signature Standard (DSS). FIPS 186–4 specifies three techniques for the generation and verification of digital signatures that can be used for the protection of data: The Digital Signature Algorithm (DSA), the Elliptic Curve Digital Signature Algorithm (ECDSA) and the Rivest-Shamir Adelman Algorithm (RSA). This revision includes a clarification of terms, a reduction of restrictions on the use of random number generators and the retention and use of prime number generation seeds, a correction of wording and typographical errors, and further aligns the FIPS with Key Cryptography Standard (PKCS) #1. FIPS 186–4 is available at *http://csrc.nist.gov/publications/PubsFIPS.html.*

DATES: The changes are effective on July 19, 2013.

FOR FURTHER INFORMATION CONTACT: Elaine Barker (301) 975–2911, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8930, Gaithersburg, MD 20899–8930, email: *Elaine.Barker@nist.gov.*

SUPPLEMENTARY INFORMATION: FIPS 186, first published on May 19, 1994 (59 FR 26208), specified a digital signature algorithm (DSA) to generate and verify digital signatures. Later revisions (FIPS 186–1, which was published in the **Federal Register** on December 15, 1998 (63 FR 69049) and FIPS 186–2, which was published on February 15, 2000 (65 FR 7507)) adopted two additional algorithms: The Elliptic Curve Digital Signature Algorithm (ECDSA) and the RSA digital signature algorithm. FIPS 186–3, which was adopted on June 9, 2009 (74 FR 27287), increased the key sizes allowed for DSA, provided additional requirements for the use of ECDSA and RSA, and included requirements for obtaining the assurances necessary for valid digital signatures. FIPS 186–3 also replaced the specifications for random number generators that had been provided in the previous versions of the FIPS with a reference to SP 800–90 for obtaining random numbers.

The changes to FIPS 186–3 include: (1) Clarifications of terms used within previous versions of the FIPS, (2) allowing the use of any random bit/number generator that is approved for use in FIPS 140–2-validated modules, (3) reducing restrictions on the retention and use of prime number generation seeds for generating RSA key pairs, (4) correcting statements regarding the generation of the integer *k* for DSA and ECDSA, (5) correcting a typological error in the processing steps for ECDSA, (6) correcting the wording for the criteria for generating RSA key pairs, and (7) aligning the specification for the use of a salt in the RSASSA–PSS digital signature scheme with Public Key Cryptography Standard (PKCS) #1.

NIST published a **Federal Register** Notice (77 FR 21538) on April 10, 2012 to request public comments on the proposed revisions to FIPS 186–3. We received two sets of comments from private sector organizations. The following summarizes the comments received during the public comment period, and includes NIST's response to each comment:

Comment: One commenter stated that the informative text in Section 5 indicates that the NIST-recommended elliptic curves have a cofactor of one, whereas, for the ten binary curves, the cofactors actually vary from two to four.

Response: That informative text was not included in FIPS 186–4, as the statement is not critical to the intent of the change.

Comment: One commenter stated that the definition of len(*a*) given in Section 2.3 of FIPS 186–3 is not sufficient, since it begs the question about whether or not leading zero bits are counted in the length.

Response: The FIPS was modified to include a revised definition for len(*a*), as suggested by the commenter.

Comment: One commenter stated that Table 1 of Section 6.1.1 of FIPS 186–3 includes an incorrect expression for the bit length of powers of two.

Response: As this expression is not critical to the table, NIST deleted the expression from the FIPS.

Comment: One commenter stated that in Appendix B.3.1, Table B.1 of FIPS 186–3, the inequality operators are confusing. These table entries should be replaced by explicit minimum and maximum values.

Response: NIST considered and rejected the request, as the table entries are specified correctly.

Revised FIPS 186–4 is available electronically from the NIST Web site at: *http://csrc.nist.gov/publications/fips/index.html.*

Authority: In accordance with the Information Technology Management Reform Act of 1996 (Pub. L. 104–106) and the Federal Information Security Management Act of 2002 (FISMA) (Pub. L. 107–347), the Secretary of Commerce is authorized to approve Federal Information Processing Standards (FIPS). NIST activities to develop computer security standards to protect federal sensitive (unclassified) information systems are undertaken pursuant to specific responsibilities assigned to NIST by section 20 of the National Institute of Standards and Technology Act (15 U.S.C. 278g–3), as amended.

E.O. 12866: This notice has been determined not to be significant for the purposes of E.O. 12866.

Dated: July 15, 2013.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2013–17396 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC767

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of availability.

SUMMARY: This notice advises the public that three direct take permits have been issued pursuant to the Endangered Species Act of 1973 (ESA) for operation,

monitoring, and evaluation of hatchery programs rearing and releasing spring Chinook salmon in the Wenatchee River basin of Washington state, and that the decision documents are available upon request.

DATES: Permits 18118, 18120, and 18121 were issued on July 2, 2013, subject to certain conditions set forth therein. Subsequent to issuance, the necessary countersignatures by the applicants were received. The permits expire on July 1, 2026.

ADDRESSES: Requests for copies of the decision documents or any of the other associated documents should be directed to the Salmon Management Division, NOAA's National Marine Fisheries Service, 1201 NE Lloyd Blvd., Suite 1100, Portland, OR97232. The documents are also available on the Internet at *www.nwr.noaa.gov*.

FOR FURTHER INFORMATION CONTACT: Amilee Wilson, Lacey, WA, at phone number: (360) 753–5820, email: *amilee.wilson@noaa.gov*

SUPPLEMENTARY INFORMATION: This notice is relevant to the following species and evolutionarily significant units (ESUs) pursuant to section 10 (a)(1)(A) of the Endangered Species Act.

Chinook salmon (*Oncorhynchus tshawytscha*): endangered, naturally produced and artificially propagated Upper Columbia River spring.

Dated: July 16, 2013.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–17397 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC763

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; Public Meetings.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a meeting of the Standing, Special Mackerel and Special Reef Fish Scientific and Statistical Committees (SSC).

DATES: The meeting will be held from 1 p.m. on Tuesday, August 6 until 12 noon on Thursday, August 8, 2013.

ADDRESSES: The meeting will be held at the Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL, 33607.

FOR FURTHER INFORMATION CONTACT: Mr. Steven Atran, Senior Fishery Biologist, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630; fax: (813) 348–1711; email: *steven.atran@gulfcouncil.org.*

SUPPLEMENTARY INFORMATION: The items of discussion in the committee meeting agendas are as follows:

Standing and Special Mackerel SSC Agenda, Tuesday, August 6, 2013, 1 p.m. until 3 p.m.

1. Introductions and Adoption of Mackerel SSC Agenda
2. Approval of May 29, 2013 Standing and Special Mackerel SSC summary minutes
3. SEDAR 28 Spanish mackerel benchmark assessment results
   a. Assessment results based on 30% SPR proxy for MSY
   b. Review of weighted average PDFs
   c. Consideration for approval of assessment
   d. Recommendation of ABC
4. Overview of ongoing Coastal Migratory Pelagics Amendments
   a. CMP Amendment 19—Bag limit sales, trip limits, latent gill net permits
   b. CMP Amendment 20—Boundaries, transit provision
5. Other business

Standing and Special Reef Fish SSC Agenda, Tuesday, August 6, 2013, 3 p.m. Until 5 p.m.; Wednesday, August 7, 2013, 8:30 a.m. Until 5 p.m.; Thursday, August 8, 2013, 8:30 a.m. Until 12 Noon

1. Approval of May 29–31, 2013 Standing and Special Reef Fish SSC summary minutes
2. MRIP Revisions of OFLs and ABCs for Several Species and Species Groupings
   a. Summary of Draft Framework Action
   b. Review of methodology for revising OFLs and ABCs
   c. Recommendations for OFLs and ABCs
3. Gray Triggerfish Review
   a. Updated indices of abundance and yield projections
   b. Consideration of ABC revision for 2014
4. Red Snapper 2013–2015 ABCs under 2013 Quota Alternatives
   a. Yield projections
   b. Consideration of ABC revision for 2014—Patterson
5. ABC Control Rule Revisions
   a. Tier structure of ABC control rule
   b. Tier 3 revisions (e.g., Martell et al.)
   c. Incorporating Scientific Uncertainty into the PDF
   d. Other control rule considerations
6. Overview of ongoing Reef Fish Actions
   a. Red snapper allocation
   b. Red snapper IFQ revisions
   c. Amendment 39—Regional management of recreational red snapper
   d. Intersector trading of allocations
   e. Definition of for-hire fishing
7. Selection of SSC representative at August 26–30, 2013 Council meeting
8. Other business
   a. Review of SEDAR Assessment Schedule/Priorities

For meeting materials see folder ''SSC meeting—2013–08'' on Gulf Council ftp server: *http://ftp.gulfcouncil.org?user=anonymous;* or by calling (813) 348–1630.

Although other non-emergency issues not on the agenda may come before the Scientific and Statistical Committees for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during these meetings. Actions of the Scientific and Statistical Committees will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 16, 2013.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–17332 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC765

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 32 Assessment Workshop webinars.

SUMMARY: The SEDAR 32 assessment of the South Atlantic stock of Gray Triggerfish will consist of: A Data Workshop; a series of Assessment webinars; and a Center for Independent Experts (CIE) Desk Review. See **SUPPLEMENTARY INFORMATION.**

DATES: SEDAR 32 additional Gray Triggerfish Assessment webinars will be held from 1 p.m. until 5 p.m. on the following dates: August 14, 2013; September 11, 2013; September 25, 2013; October 17, 2013; October 30, 2013; November 13, 2013; December 11, 2013; and January 8, 2014.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julia Byrd at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator; telephone: (843) 571–4366; email: *julia.byrd@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Process utilizing a Workshop or a Desk Review. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop or through a CIE Desk Review. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. The products of the CIE Desk Review are individual reports documenting each reviewer's opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Assessment webinars are as follows:

1. Participants will employ assessment models to evaluate stock status, estimate population benchmarks and management criteria, and project future conditions. The assessment models will use the recommended datasets from the Data Workshop.

2. Participants will recommend the most appropriate methods and configurations for determining stock status and estimating population parameters.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SEDAR office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801.

Dated: July 16, 2013.

William D. Chappell,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–17399 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC764

Fisheries of the South Atlantic; Southeast Data, Assessment and Review (SEDAR); Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 32 Review Workshop for South Atlantic Blueline Tilefish (*Caulolatilus microps*) and SEDAR 32A Review Workshop for Gulf of Mexico Menhaden (*Brevoortia patronus*).

SUMMARY: The SEDAR 32 and 32A review of the South Atlantic stock of Blueline Tilefish and Gulf of Mexico stock of Menhaden will consist of one workshop. See **SUPPLEMENTARY INFORMATION.**

DATES: The SEDAR 32 and 32A Review Workshop will be held from August 27–30, 2013. The workshop will begin at 9 a.m. and conclude no later than 1 p.m. EDT on the final day. See **SUPPLEMENTARY INFORMATION.**

ADDRESSES:

Meeting address: The SEDAR 32 and 32A Review Workshops will be held at the Crystal Coast Civic Center, 3505 Arendell Street, Morehead City, NC 28557; telephone: (252) 247–3883. The Review Workshop is open to members of the public.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator; telephone: (843) 571–4366; email: *julia.byrd@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA

Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, the Atlantic and Gulf States Marine Fisheries Commissions, NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Review Workshop are as follows:

Panelists will review the assessment and document their comments and recommendations in a Consensus Summary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SEDAR office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801.

Dated: July 16, 2013.

William D. Chappell,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–17398 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC646

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to a Wharf Construction Project

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that we have issued an incidental harassment authorization (IHA) to the U.S. Navy (Navy) to incidentally harass, by Level B harassment only, six species of marine mammals during construction activities associated with a wharf construction project in Hood Canal, Washington.

DATES: This authorization is effective from July 16, 2013, through February 15, 2014.

ADDRESSES: A copy of the IHA and related documents may be obtained by visiting the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm* or by writing to Michael Payne, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. A memorandum describing our adoption of the Navy's Environmental Impact Statement (2011) and our associated Record of Decision, prepared pursuant to the National Environmental Policy Act, are also available at the same site. Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the U.S. can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization. Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: ''Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].''

Summary of Request

We received an application on December 10, 2012, from the Navy for the taking of marine mammals incidental to pile driving and removal in association with a wharf construction project in the Hood Canal at Naval Base Kitsap in Bangor, WA (NBKB). The Navy submitted a revised version of the application on May 6, 2013, which we deemed adequate and complete. The wharf construction project is a multi-year project; this IHA would cover only the second year of the project, from July 16, 2013, through February 15, 2014. We previously issued an IHA to the Navy for the first year of work associated with this project; that IHA was valid from July 16, 2012, through February 15, 2013 (77 FR 42279; July 18, 2012). Pile driving and removal activities in a given year may occur only within an approved in-water work window from July 16-February 15. Six species of marine mammals may be affected by the specified activities: Steller sea lion (*Eumetopias jubatus monteriensis*), California sea lion (*Zalophus californianus californianus*), harbor seal (*Phoca vitulina richardii*), killer whale (transient only; *Orcinus orca*), Dall's porpoise (*Phocoenoides dalli dalli*), and harbor porpoise (*Phocoena phocoena vomerina*). These species may occur year-round in the Hood Canal, with the exception of the Steller sea lion, which is typically present only from fall to late spring (October to mid-April), and the California sea lion, which is typically present from late summer to late spring (August to early June). The killer whale and Dall's porpoise have been observed in Hood Canal but do not regularly occur there.

NBKB provides berthing and support services to Navy submarines and other fleet assets. The Navy plans to continue construction of the Explosive Handling Wharf #2 (EHW–2) facility at NBKB in order to support future program requirements for submarines berthed at NBKB. The Navy has determined that construction of EHW–2 is necessary because the existing EHW alone will not be able to support future program requirements. Under the specified activities—which include only the portion of the project that would be completed under this 1-year IHA—a maximum of 195 pile driving days would occur. All piles will be driven with a vibratory hammer for their initial embedment depths, while select piles may be finished with an impact hammer for proofing, as necessary. Proofing involves striking a driven pile with an impact hammer to verify that it provides the required load-bearing capacity, as indicated by the number of hammer blows per foot of pile advancement. Sound attenuation measures (i.e., bubble curtain) will be used during all impact hammer operations.

For pile driving activities, the Navy used thresholds recommended by NMFS for assessing project impacts, outlined later in this document. The Navy assumed practical spreading loss and used empirically-measured source levels from other similar pile driving events to estimate potential marine mammal exposures. Predicted exposures are outlined later in this document. The calculations predict that only Level B harassment will occur associated with pile driving or construction activities.

Description of the Specified Activity

NBKB is located on the Hood Canal approximately twenty miles (32 km) west of Seattle, Washington (see Figures 2–1 through 2–4 in the Navy's application). The specified activities with the potential to cause harassment of marine mammals within the waterways adjacent to NBKB, under the MMPA, are vibratory and impact pile driving operations, as well as vibratory removal of falsework piles, associated with the wharf construction project. The specified activities that would be authorized by this IHA would occur between July 16, 2013, and February 15, 2014. The allowable season for in-water work, including pile driving, at NBKB is July 16 through February 15, which was established by the Washington Department of Fish and Wildlife in coordination with NMFS and the U.S. Fish and Wildlife Service (USFWS) to protect juvenile salmon protected under the Endangered Species Act (ESA). Additional details regarding the specified geographic area and construction plans for the project were described in our **Federal Register** notice of proposed authorization (78 FR 29705; May 21, 2013; hereafter, the FR notice); please see that document or the Navy's application for more information.

As part of the Navy's sea-based strategic deterrence mission, the Navy Strategic Systems Programs directs research, development, manufacturing, testing, evaluation, and operational support for the TRIDENT Fleet Ballistic Missile program. Development of necessary facilities for handling of explosive materials is part of these duties. The EHW–2 will consist of two components: (1) The wharf proper (or Operations Area), including the warping wharf; and (2) two access trestles. Please see Figures 1–1 and 1–2 of the Navy's application for conceptual and schematic representations of the EHW–2.

For the entire project, a total of up to 1,250 permanent piles ranging in size between 24–48 in (0.6–1.2 m) in diameter will be driven in-water to construct the wharf, with up to three vibratory rigs and one impact driving rig operating simultaneously. Construction will also involve temporary installation of up to 150 falsework piles used as an aid to guide permanent piles to their proper locations. Falsework piles, which are removed upon installation of the permanent piles, will likely be steel pipe piles and will be driven and removed using a vibratory driver. It has not been determined exactly what parts or how much of the project will be constructed in any given year; however, a maximum of 195 days of pile driving may occur per in-water work window. The analysis contained herein is based upon the maximum of 195 pile driving days, rather than any specific number of piles driven. Table 1 summarizes the number and nature of piles required for the entire project, rather than what subset of piles may be expected to be driven during the second year of construction planned for this IHA.

TABLE 1—SUMMARY OF PILES REQUIRED FOR WHARF CONSTRUCTION

[in total]

Feature	Quantity
Total number of permanent in-water piles.	Up to 1,250
Size and number of main wharf piles.	24-in: 140 36-in: 157 48-in: 263
Size and number of warping wharf piles.	24-in: 80 36-in: 190
Size and number of lightning tower piles.	24-in: 40 36-in: 90
Size and number of trestle piles.	24-in: 57 36-in: 233
Falsework piles	Up to 150, 18- to 24-in
Maximum pile driving duration.	195 days (under 1-year IHA)

Pile installation will employ vibratory pile drivers to the greatest extent possible, and the Navy anticipates that most piles will be able to be vibratory driven to within several feet of the required depth. Pile drivability is, to a large degree, a function of soil conditions and the type of pile hammer. Recent experience at two other construction locations along the NBKB waterfront indicates that most piles should be able to be driven with a vibratory hammer to proper embedment depth. However, difficulties during pile driving may be encountered as a result

of obstructions that may exist throughout the project area. Such obstructions may consist of rocks or boulders within the glacially overridden soils. If difficult driving conditions occur, increased usage of an impact hammer will be required. The Navy estimates that up to five piles may be proofed in a day, requiring a maximum total of 1,000 strikes from the impact hammer. Under a worst-case scenario (i.e., difficult subsurface driving conditions encountered), as many as three piles might require driving with an impact hammer to their full embedment depth. With proofing of two additional piles, this scenario would result in as many as 6,400 impact pile strikes in a day. Please see the FR notice (78 FR 29705; May 21, 2013) for more detail.

Impact pile driving during the first half of the in-water work window (July 16 to September 15) will only occur between 2 hours after sunrise and 2 hours before sunset to protect breeding marbled murrelets (*Brachyramphus marmoratus;* an ESA-listed bird under the jurisdiction of the USFWS). Between September 16 and February 15, construction activities occurring in the water will occur during daylight hours (sunrise to sunset). Other construction (not in-water) may occur between 7 a.m. and 10 p.m., year-round.

Description of Work Completed

During the first in-water work season, and during the period of validity of the first IHA issued for this project, the contractor completed installation of 184 piles to support the main segment of the access trestle. Driven piles ranged in size from 24- to 36-in diameter. A maximum of two vibratory rigs were operated concurrently and only one impact hammer rig was operated at a time. Due to delays in beginning construction, pile driving did not begin until September 28, 2012, and occurred on 78 days between that date and the end of the work window on February 15, 2013. Primarily vibratory driving was conducted; of the 78 pile driving days, both vibratory and impact driving occurred on 19 days and impact driving alone occurred on only three days. During the second season, installation of the piling for the wharf deck is expected to be completed, and it is likely that contractors will more closely approach the notional activity levels contemplated in this analysis (i.e., 195 days total driving, with both impact and vibratory driving occurring on each day). However, the activity level is the maximum possible, and unforeseen delays inherent to any construction schedule mean that it is not likely that the maximum activity level will actually occur.

Description of Sound Sources and Distances to Thresholds

An in-depth description of sound sources in general was provided in the FR notice (78 FR 29705; May 21, 2013). Significant sound-producing in-water construction activities associated with the project include impact and vibratory pile driving and vibratory pile removal.

NMFS uses generic sound exposure thresholds to determine when an activity that produces sound might result in impacts to a marine mammal such that a take by harassment might occur. To date, no studies have been conducted that examine impacts to marine mammals from pile driving sounds from which empirical sound thresholds have been established. Current NMFS practice (in relation to the MMPA) regarding exposure of marine mammals to sound is that cetaceans and pinnipeds exposed to sound levels of 180 and 190 dB root mean square (rms; note that all underwater sound levels in this document are referenced to a pressure of 1 μPa) or above, respectively, are considered to have been taken by Level A (i.e., injurious) harassment, while behavioral harassment (Level B) is considered to have occurred when marine mammals are exposed to sounds at or above 120 dB rms for continuous sound (such as will be produced by vibratory pile driving) and 160 dB rms for pulsed sound (produced by impact pile driving), but below injurious thresholds. For airborne sound, pinniped disturbance from haul-outs has been documented at 100 dB (unweighted) for pinnipeds in general, and at 90 dB (unweighted) for harbor seals (note that all airborne sound levels in this document are referenced to a pressure of 20 μPa). NMFS uses these levels as guidelines to estimate when harassment may occur. NMFS is currently revising these acoustic guidelines. For more information on that process, please visit *http://www.nmfs.noaa.gov/pr/acoustics/guidelines.htm.*

Sound levels can be greatly reduced during impact pile driving using sound attenuation devices. The Navy is required to use sound attenuation devices for all impact pile driving, and has elected to use bubble curtains. Bubble curtains work by creating a column of air bubbles rising around a pile from the substrate to the water surface. The air bubbles absorb and scatter sound waves emanating from the pile, thereby reducing the sound energy. A confined bubble curtain contains the air bubbles within a flexible or rigid sleeve made from plastic, cloth, or pipe. Confined bubble curtains generally offer higher attenuation levels than unconfined curtains because they may physically block sound waves and they prevent air bubbles from migrating away from the pile.

The literature presents a wide array of observed attenuation results for bubble curtains (e.g., Oestman *et al.,* 2009, Coleman, 2011, Caltrans, 2012). The variability in attenuation levels is due to variation in design, as well as differences in site conditions and difficulty in properly installing and operating in-water attenuation devices. As a general rule, reductions of greater than 10 dB cannot be reliably predicted. In the acoustic modeling conducted by the Navy to assess project impacts, they assumed that use of a bubble curtain could reasonably result in 10 dB of attenuation, and reduced the proxy source levels accordingly. Since that initial assessment was completed, site-specific measurements from the Navy's 2011 Test Pile Project (TPP; Illingworth & Rodkin, Inc., 2012), as well as difficulties encountered by the Navy's contractors in properly deploying bubble curtains, have shown that 8 dB (or possibly less) may be a more realistic assumption regarding average SPL (rms) reduction. However, the prior assumption of 10 dB attenuation is carried forward here. The Navy has committed to implementing conservative shutdown zones, as indicated by empirical, site-specific measurements that are larger than those predicted from the modeling results in order to ensure that the 180/190 dB zones are encompassed by protective measures. Prior to any future IHAs, we will work with the Navy to more accurately account for the mitigating effects of bubble curtain usage. In addition, to avoid loss of attenuation from design and implementation errors, the Navy has incorporated contractual requirements regarding specific bubble curtain design specifications, including testing requirements for air pressure and flow prior to initial impact hammer use, and a requirement for placement on the substrate.

Distance to Sound Thresholds

Pile driving generates underwater noise that can potentially result in disturbance to marine mammals in the project area. Please see the FR notice (78 FR 29705; May 21, 2013) for a detailed description of the calculations and information used to estimate distances to relevant threshold levels. Transmission loss, or the decrease in acoustic intensity as an acoustic

pressure wave propagates out from a source, was estimated as so-called ''practical spreading loss''. This model follows a geometric propagation loss based on the distance from the pile, resulting in a 4.5 dB reduction in level for each doubling of distance from the source. In the model used here, the sound pressure level (SPL) at some distance away from the source (e.g., driven pile) is governed by a measured source level, minus the transmission loss of the energy as it dissipates with distance.

The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. A large quantity of literature regarding SPLs recorded from pile driving projects is available for consideration. In order to determine reasonable SPLs and their associated effects on marine mammals that are likely to result from pile driving at NBKB, studies with similar properties to the specified activity were evaluated, including measurements conducted for driving of steel piles at NBKB as part of the TPP (Illingworth & Rodkin, Inc., 2012). During the TPP, SPLs from driving of 24-, 36-, and 48-in piles by impact and vibratory hammers were measured. Sound levels associated with vibratory pile removal are assumed to be the same as those during vibratory installation (Reyff, 2007)—which is likely a conservative assumption—and have been taken into consideration in the modeling analysis. Overall, studies which met the following parameters were considered: (1) Pile size and materials: Steel pipe piles (30–72 in diameter); (2) Hammer machinery: Vibratory and impact hammer; and (3) Physical environment: shallow depth (less than 100 ft [30 m]).

Representative data for pile driving SPLs recorded from similar construction activities in recent years were presented in the FR notice (78 FR 29705; May 21, 2013). For impact pile driving, distances to the marine mammal sound thresholds were calculated with the assumption of a 10 dB reduction in source levels from the use of a bubble curtain. For impact driving, a source value of 195 dB RMS re 1µPa at 10 m (185 dB used as proxy value) was the average value reported from the listed studies, and is consistent with measurements from the TPP and Carderock Pier pile driving projects at NBKB, which had similar pile materials (48- and 42-inch hollow steel piles, respectively), water depth, and substrate type as the EHW–2 project site. For vibratory pile driving, the Navy selected the most conservative value (72-in piles; 180 dB rms re 1µPa at 10 m) available when initially assessing EHW–2 project impacts, prior to the first year of the project. Since then, data from the TPP have become available that indicate, on average, a lower source level for vibratory pile driving (172 dB rms re 1µPa for 48-inch steel piles). However, for consistency we have maintained the initial conservative assumption regarding source level for vibratory driving. All calculated distances to and the total area encompassed by the marine mammal sound thresholds are provided in Table 2. Predicted distances to thresholds for different sources are shown in Figures 6–1 and 6–2 of the Navy's application.

Under the maximum construction scenario, up to three vibratory drivers will operate simultaneously with one impact driver. Although radial distance and area associated with the zone ensonified to 160 dB rms (the behavioral harassment threshold for pulsed sounds, such as those produced by impact driving) are presented in Table 2 for reference, this zone would be subsumed by the 120 dB rms zone produced by vibratory driving. Thus, behavioral harassment of marine mammals associated with impact driving is not considered further here. Since the 160 dB threshold and the 120 dB threshold both indicate behavioral harassment, pile driving effects in the two zones are equivalent. Although such a day is not planned, if only the impact driver is operated on a given day, incidental take on that day would likely be lower because the area ensonified to levels producing Level B harassment would be smaller (although actual take would be determined by the numbers of marine mammals in the area on that day). The use of multiple vibratory rigs at the same time will result in a small additive effect with regard to produced SPLs; however, because the sound field produced by vibratory driving will be truncated by land in the Hood Canal, no increase in actual sound field produced will occur. There will be no overlap in the 190/180-dB sound fields produced by rigs operating simultaneously.

TABLE 2—CALCULATED DISTANCE(S) TO AND AREA ENCOMPASSED BY UNDERWATER MARINE MAMMAL SOUND THRESHOLDS DURING PILE INSTALLATION

Threshold	Distance (m)	Area, km[2]
Impact driving, pinniped injury (190 dB)	4.9	0.0001
Impact driving, cetacean injury (180 dB)	22	0.002
Impact driving, disturbance[2] (160 dB)	724	1.65
Vibratory driving, pinniped injury (190 dB)	2.1	< 0.0001
Vibratory driving, cetacean injury (180 dB)	10	0.0003
Vibratory driving, disturbance (120 dB)	[3] 13,800	[3] 41.4 (15.98)

[1] SPLs used for calculations were: 185 dB for impact and 180 dB for vibratory driving.
[2] Area of 160-dB zone presented for reference. Estimated incidental take calculated on basis of larger 120-dB zone.
[3] Hood Canal average width at site is 2.4 km (1.5 mi), and is fetch limited from N to S at 20.3 km (12.6 mi). Calculated range (over 222 km) is greater than actual sound propagation through Hood Canal due to intervening land masses. 13.8 km (8.6 mi) is the greatest line-of-sight distance from pile driving locations unimpeded by land masses, which would block further propagation of sound. 15.98 km is the approximate actual area encompassing the 120-dB zone, as demonstrated by modeling results.

Hood Canal does not represent open water, or free field, conditions. Therefore, sounds will attenuate as they encounter land masses or bends in the canal. As a result, the calculated distance and areas of impact for the 120 dB threshold cannot actually be attained at the project area. See Figure 6–1 of the Navy's application for a depiction of the size of areas in which each underwater sound threshold is predicted to occur at the project area due to pile driving.

Pile driving can generate airborne sound that could potentially result in disturbance to marine mammals (specifically, pinnipeds) which are hauled out or at the water's surface. As a result, the Navy analyzed the potential for pinnipeds hauled out or swimming at the surface near NBKB to be exposed to airborne SPLs that could result in Level B behavioral harassment. A spherical spreading loss model (i.e., 6 dB reduction in sound level for each

doubling of distance from the source), in which there is a perfectly unobstructed (free-field) environment not limited by depth or water surface, is appropriate for use with airborne sound and was used to estimate the distance to the airborne thresholds.

As was discussed for underwater sound from pile driving, the intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. In order to determine reasonable airborne SPLs and their associated effects on marine mammals that are likely to result from pile driving at NBKB, studies with similar properties to the Navy's project, as described previously, were evaluated.

Based on in-situ recordings from similar construction activities, the Navy previously considered the maximum airborne sound levels that would result from impact and vibratory pile driving as 118 dB and 96 dB (at 15 m), respectively (Blackwell *et al.,* 2004; Laughlin, 2010). During the TPP, impact driving was measured at 109 dB and vibratory driving at 102 dB (at 15 m). We have retained the previous values for impact assessment because the value for impact driving, as used in the combined rig scenario, results in a more conservative ZOI than does the TPP measurement. The Navy has analyzed the combined sound field produced under the multi-rig scenario and calculated the radial distances to the 90 and 100 dB airborne thresholds as 361 m and 114 m, respectively, equating to areas of 0.41 km^2 and 0.04 km^2, respectively.

There are no haul-out locations within these zones, which are encompassed by the zones estimated for underwater sound. Protective measures would be in place out to the distances calculated for the underwater thresholds, and the distances for the airborne thresholds would be covered fully by mitigation and monitoring measures in place for underwater sound thresholds. Construction sound associated with the project would not extend beyond the buffer zone for underwater sound that would be established to protect pinnipeds. No haul-outs or rookeries are located within the airborne harassment radii. See Figure 6–2 of the Navy's application for a depiction of the size of areas in which each airborne sound threshold is predicted to occur at the project area due to pile driving. We recognize that pinnipeds in water that are within the area of ensonification for airborne sound could be incidentally taken by either underwater or airborne sound or both. We consider these incidences of harassment to be accounted for in the take estimates for underwater sound.

Acoustic Monitoring

During the first year of construction for EHW–2, the Navy conducted acoustic monitoring as required under the IHA. During year one, 24- to 36-in diameter piles were primarily driven, by vibratory and impact driving. Only one 48-in pile was driven, so no data are provided for that pile size. All piles were steel pipe piles. Primary objectives for the acoustic monitoring were to characterize underwater and airborne source levels for each pile size and hammer type and to verify distances to relevant threshold levels by characterizing site-specific transmission loss. Select results are reproduced here; the interested reader may find the entire reports posted at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.*

TABLE 3—ACOUSTIC MONITORING RESULTS FROM 2012–13 ACTIVITIES AT EHW–2

Pile size (in)	Hammer type [1]	n	Underwater			Airborne	
			RL [3]	SD [4]	TL [5]	RL [6]	SD
24	Impact	41	179	24.1	18.6	103	1.0
36	Impact	26	188	5.0	14.9	102	2.2
24	Vibratory	71	163	8.3	15.3	95	3.7
36	Vibratory	113	169	4.3	16.8	103	3.2

[1] All data for impact driving include use of bubble curtain.
[2] n = sample size, or number of measured pile driving events.
[3] Received level at 10 m, presented in dB re: 1 μPa rms.
[4] Standard deviation.
[5] Transmission loss (log_{10}).
[6] Received level at 15 m, presented in dB re: 20 μPa rms (Z-weighted L_{eq}).

For vibratory driving, measured source levels were below the 180-dB threshold. Calculation of average distances to the 120-dB threshold was complicated by variability in propagation of sound at greater distances, variability in measured sounds from event to event, and the difficulty of making measurements, given noise from wind and wave action, in the far field. Also, as observed during previous monitoring events at NBKB, measured levels in shallower water at the far side of Hood Canal are sometimes louder than measurements made closer to the source in the deeper open channel. These events are unexplained. Average radial distances to the 120-dB threshold were 2,765 m for 24-in piles and 10,483 m for 36-in piles. However, the topography of Hood Canal realistically constrains distances to 7,000 m to the south of the project area. For impact driving, calculated average zones (provided for 36-in piles) were as follows: 190-dB zone at 12 m; 180-dB zone at 45 m; and 160-dB zone at 670 m. Measurements of impact driving for 24-in piles showed a high degree of variation (standard deviation of 24.1) because many of these piles were driven either on land or in extremely shallow water, while others were driven in deeper water more characteristic of typical driving conditions for EHW–2.

Sound levels during soft starts were typically lower than those levels at the initiation and completion of continuous vibratory driving. However, levels during continuous driving varied considerably and were at times lower than those produced during the soft starts. It is difficult to assign a level that describes how much lower the soft start sound levels were than continuous levels. Similarly inconclusive results were seen from monitoring associated with the TPP.

Comments and Responses

We published a notice of receipt of the Navy's application and proposed IHA in the **Federal Register** on May 21, 2013 (78 FR 29705). NMFS received comments from the Marine Mammal Commission (Commission). The Commission's comments and our responses are provided here, and the comments have been posted on the

internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.*

Comment 1: The Commission recommends that we require the Navy to re-estimate the number of harbor seal takes using more recent survey data from Tannenbaum *et al.* (2009, 2011), which is based on the total estimated population rather than the Navy's rationale of reducing the density for the proportion of seals hauled out and older data.

Response: As described in greater detail in the FR notice, there are two sources of information from which a suitable density estimate may be derived for harbor seals. These include aerial surveys of Hood Canal (358.4 km^2) conducted in 1999 and vessel-based marine wildlife surveys conducted by the Navy in nearshore waters of NBKB (3.9 km^2) during July through September 2008 and November through May 2009–10. Despite the time lapse, these survey efforts produce comparable results. Because harbor seals, unlike sea lions, form a resident population in Hood Canal and are not known to be attracted to the NBKB waterfront by any foraging or haul-out opportunity, it is the opinion of both NMFS and the Navy that it is preferable to use the density value that is derived from a survey of the entire population. The Tannenbaum *et al.* (2009, 2011) data are not based on the total estimated population, but on surveys of a very small section of Hood Canal (approximately one percent of the Hood Canal area along the NBKB waterfront).

Based on the 1999 surveys, which also form the basis for the most recent abundance estimates provided in NMFS' Stock Assessment Report for the Washington inland waters stock of harbor seals, Jeffries *et al.* (2003) estimated the abundance of harbor seals in the Hood Canal as 1,088 individuals. The resulting density is 3.04 animals/km^2; however, use of this density in estimating take would make the assumption that 100 percent of the animals would be in the water at all times. Therefore, a factor derived from Huber *et al.* (2001)—only 35 percent of seals are in the water at any given time—was applied to correct for animals out of the water and not available to be exposed to underwater sound; the resulting corrected density of seals in the water at any given time is 1.06 animals/km^2. We note here that previous analyses for Navy actions at NBKB used a corrected density of 1.31 animals/km^2 that was based on an erroneous understanding of the survey area used by Jeffries *et al.* (2003). The Navy requested that we retain the higher density for take estimation associated with this IHA because their analyses were already complete, and because the higher density would produce an overestimate of take. A separate request for incidental take authorization, for the barge mooring project at NBKB, uses the lower density estimate based off of an accurate understanding of the survey area used by Jeffries *et al.* (2003). The reason for the discrepancy was clearly explained (see page 29728 at 78 FR 29705; May 21, 2013).

The Commission disagrees with this approach because of their contention that (1) an instantaneous estimate of animals in the water at a given time does not produce an accurate assessment of the number of individuals that may enter the water over the daily duration of the activity and (2) use of the uncorrected density would be consistent with our decision to base the number of takes of sea lions on average monthly maximum abundance estimates at NBKB haul-out sites, under the assumption that each individual present would enter the water and therefore be exposed to underwater sound that may result in behavioral harassment at some point on any given day. With regard to the second point, we note that consistency between approaches for sea lions and for harbor seals would not be appropriate. Sea lions are attracted to the NBKB waterfront by the presence of submarines and other haul-out opportunities. Site-specific data therefore better reflects the nature of sea lion occurrence than does a regional density. With regard to the first point, as acknowledged in the FR notice (78 FR 29705; May 21, 2013), we recognize that over the course of a day, while the proportion of animals in the water may not vary significantly, different individuals may enter and exit the water. That is, it is probable that greater than 35 percent of seals will enter the water at some point during the day. No data exist regarding fine-scale harbor seal movements within the project area on time durations of less than a day, thus precluding an assessment of ingress or egress of different animals through the action area. As such, it is impossible, given available data, to determine exactly what number of individuals above 35 percent may potentially be exposed to underwater sound. Therefore, we are left to make a decision, on the basis of limited available information, regarding which of these two scenarios (i.e., 100 percent vs. 35 percent of harbor seals are in the water and exposed to sound) produces a more accurate estimate of the potential incidents of take.

First, we understand that hauled-out harbor seals are necessarily at haul-outs. No significant harbor seal haul-outs are located within or near the action area. Harbor seals observed in the vicinity of the NBKB shoreline are rarely hauled-out (for example, in formal surveys during 2007–08, approximately 86 percent of observed seals were swimming), and when hauled-out, they do so opportunistically (i.e., on floating booms rather than established haul-outs). Harbor seals are typically unsuited for using manmade haul-outs at NBKB, which are used by sea lions. Primary harbor seal haul-outs in Hood Canal are located at significant distance (20 km or more) from the action area in Dabob Bay or further south (see Figure 4–1 in the Navy's application), meaning that animals casually entering the water from haul-outs or flushing due to some disturbance at those locations would not be exposed to underwater sound from the project; rather, only those animals embarking on foraging trips and entering the action area may be exposed.

Second, we know that harbor seals in Hood Canal are not likely to have a uniform distribution as is assumed through use of a density estimate, but are likely to be relatively concentrated near areas of interest such as the haul-outs found in Dabob Bay or foraging areas. The majority of the action area consists of the Level B harassment zone in deeper waters of Hood Canal; past observations from surveys and required monitoring have confirmed that harbor seals are less abundant in these waters.

Third, a typical pile driving day (in terms of the actual time spent driving) is much shorter than the 8–15 hours cited by the Commission as a representative pile driving day. Construction scheduling and notional production rates in concert with typical delays mean that hammers are active for only some small fraction of time on pile driving ''days''. During the first year of construction for EHW–2, vibratory pile driving occurred on 75 days, but only for an approximate total time of 71 hours.

What we know tells us that (1) The turnover of harbor seals (in and out of the water) is occurring primarily outside the action area and would not be expected to result in a greater number of individuals entering the action area within a given day and being harassed than is assumed; (2) there are likely to be significantly fewer harbor seals in the majority of the action area than would be indicated by the uncorrected density; and (3) pile driving actually occurs over a limited timeframe on any given day, reducing the amount of time over which new individuals might enter the action area within a given day. These factors lead us to believe that the corrected

density is likely to more closely approximate the number of seals that may be found in the action area than does the uncorrected density, and there are no existing data that would indicate that the proportion of individuals entering the water within the predicted area of effect during pile driving would be dramatically larger than 35 percent. Therefore, the Commission's suggestion that 100 percent of the population be used to estimate density would likely result in a gross exaggeration of potential take. Moreover, because the Navy is typically unable to determine from field observations whether the same or different individuals are being exposed, each observation is recorded as a new take, although an individual theoretically would only be considered as taken once in a given day.

Finally, we note that during the course of four previous IHAs over two years (2011–12), the Navy has been authorized for 6,725 incidents of incidental harassment (corrected for actual number of pile driving days). The total estimate of actual incidents of take (observed takes and observations extrapolated to unobserved area) was 868. This is almost certainly negatively biased, but the huge disparity does provide confirmation that we are not significantly underestimating takes.

Comment 2: The Commission recommends that we require the Navy to implement soft start procedures after 15 minutes if pile driving or removal is delayed or shut down because of the presence of a marine mammal within or approaching the shutdown zone.

Response: We do not believe the recommendation would be effective in reducing the number or intensity of incidents of harassment—in fact, we believe that implementation of this recommendation may actually increase the number of incidents of harassment by extending the overall project duration—while imposing a high cost in terms of operational practicability. We note here that, while the Commission recommends use of the measure to avoid serious injury (i.e., injury that will result in death of the animal), such an outcome is extremely unlikely even in the absence of any mitigation measures (as described in the FR notice at 78 FR 29705; May 21, 2013). Given that conclusion, we address our response to the potential usefulness of the measure in avoidance of non-serious injury (i.e., Level A harassment).

Soft start is required for the first impact pile driving of each day and, subsequently, after any impact pile driving stoppage of 30 minutes or greater. The purpose of a soft start is to provide a ''warning'' to animals by initiating the production of underwater sound at lower levels than are produced at full operating power. This warning is presumed to allow animals the opportunity to move away from an unpleasant stimulus and to potentially reduce the intensity of behavioral reactions to noise or prevent injury of animals that may remain undetected in the zone ensonified to potentially injurious levels. However, soft start requires additional time, resulting in a larger temporal footprint for the project. That is, soft start requires a longer cumulative period of pile driving (i.e., hours) but, more importantly, leads to a longer overall duration (i.e., more days on which pile driving occurs). In order to maximize the effectiveness of soft start while minimizing the implementation costs, we require soft start after a period of extended and unobserved relative silence (i.e., at the beginning of the day, after the end of the required 30-minute post-activity monitoring period, or after 30 minutes with no impact driving). It is after these periods that marine mammals are more likely to closely approach the site (because it is relatively quiet) and less likely to be observed prior to initiation of the activity (because continuous monitoring has been interrupted).

The Commission justifies this recommendation on the basis of the potential for undetected animals to remain in the shutdown zone, and describes various biases (i.e., availability, detection, and perception) on an observer's ability to detect an animal. We do not believe that time is a factor in determining the influence of these biases on the probability of observing an animal in the shutdown zone. That is, an observer is not more likely to detect the presence of an animal at the 15-minute mark of continuous monitoring than after 30 minutes (it is established that soft start is required after any unmonitored period). Therefore, requiring soft start after 15 minutes (i.e., more soft starts) is not likely to result in increased avoidance of injury. Finally, we do not believe that the use of soft start may be expected to appreciably reduce the potential for injury where the probability of detection is high (e.g., small, shallow zones with good environmental conditions). Rather, the primary purpose of soft start under such conditions is to reduce the intensity of potential behavioral reactions to underwater sound in the disturbance zone.

As noted by the Commission, there are multiple reasons why marine mammals may remain in a shutdown zone and yet be undetected by observers. Animals are missed because they are underwater (availability bias) or because they are available to be seen, but are missed by observers (perception and detection biases) (e.g., Marsh and Sinclair, 1989). Negative bias on perception or detection of an available animal may result from environmental conditions, limitations inherent to the observation platform, or observer ability. While missed detections are possible in theory, this would require that an animal would either (a) remain submerged (i.e., be unavailable) for periods of time approaching or exceeding 15 minutes and/or (b) remain undetected while at the surface. We provide further site-specific detail below.

First, environmental conditions in the Hood Canal are typically excellent and, unlike the moving aerial or vessel-based observation platforms for which detectability bias is often a concern, the observers here will be positioned in the most suitable locations to ensure high detectability (randomness of observations is not a concern, as it is for abundance sampling). We believe that the probability of detecting animals within the shutdown zones proposed for this action approaches 100 percent. The 190 dB zone for pinnipeds is small, with radial distance of only 20 m, while the 180 dB zone for cetaceans (85 m) is notional only—no cetaceans have ever been recorded as entering the security area bounded by the floating port security barrier. Regarding availability, the most abundant species, and therefore the species most likely to be present in the mitigation zones, are the harbor seal and California sea lion.

It is generally unlikely that a pinniped would remain within approximately 20 m of an active construction zone, in the absence of any known foraging opportunities or other attractant of any significance, for an extended period of time. However, some harbor seals have been known to frequent the areas surrounding existing wharves at NBKB. Even when this situation does occur, the possibility that individuals would remain submerged for a period of time exceeding 15 minutes is discountable.

Dive behavior for harbor seals, including typical duration, is influenced by a variety of factors, such as behavioral context, local bathymetric conditions, and the specific physiological characteristics of the animal (e.g., Harkonen, 1987a,b; Eguchi and Harvey, 2005). Dive depth may be expected to correlate well with dive duration. However, Eguchi and Harvey (2005) showed that average dive durations in Monterey Bay, where available depths are much deeper than

those in the nearshore environment at NBKB, were only 4.8 and 5.5 minutes for females and males, respectively. Although fine-scale population structure exists for harbor seals on a geographic basis from California to Alaska (Carretta *et al.,* 2011), similar results have been obtained in Alaska and Washington. Dive durations for harbor seals from three locations across the Gulf of Alaska were typically less than 4 minutes across factors (Hastings *et al.,* 2004). Closer to the action area in Puget Sound waters, Suryan and Harvey (1998) reported dive depths ranging from 3.2–4.6 min. Importantly, those durations were reduced in nearshore waters similar to those in the shutdown zone (1.5–3.6 min). Conversely, dive durations were somewhat longer during milling behavior, which is sometimes observed in the action area. However, surface intervals (which ranged from 0.6–0.9 min) showed a significantly positive correlation to dive duration (Suryan and Harvey, 1998), meaning that longer dives, or periods of high availability bias, are followed by periods of relatively greater availability.

Sea lions employ a shallow epipelagic foraging strategy, and numerous studies have reported mean dive times of approximately 2 minutes for California sea lions (e.g., Feldkamp *et al.,* 1989 [mean dive time less than 3 min]; Weise *et al.,* 2006 [mean dive time 1.9 ± 1.6 min]). Kuhn *et al.* (2003) cite published values for sea lion aerobic dive limits ranging from 2.3–5.8 minutes and, while it is possible that sea lions may dive beyond these limits when foraging on the benthos, significantly longer dive durations would not be expected in shallow waters. In addition, while short surface intervals are also possible, longer values are typical of data found in the literature for animals engaged in foraging (e.g., Costa *et al.* (2007) report a mean surface interval of 1.6 minutes). Sea lions will typically spend a much greater proportion of time at the surface when not foraging, and behavioral observations in the nearshore action area show that California sea lions are typically traveling, likely to haul-out opportunities at Delta Pier.

Under the typically excellent observation conditions found in the Hood Canal, we believe that surfaced animals would be observed. Based on the foregoing factors, we have high confidence in the ability of observers to detect marine mammals in the shutdown zones estimated for this project in the Hood Canal.

Comment 3: The Commission recommends that we require the Navy to consult with the Washington State Department of Transportation and/or the California Department of Transportation to (1) determine whether soft start procedures can be used safely with the vibratory hammers that the Navy plans to use prior to eliminating the Navy's requirement to implement those measures and (2) clarify and troubleshoot the sound attenuation device implementation procedures to ensure the device's efficacy.

Response: We concur with the first part of the Commission's recommendation and will facilitate the suggested consultation. However, this cannot be accomplished prior to issuance of the IHA due to the Navy's operational needs. Accordingly, we deem vibratory soft starts to not currently be practicable due to safety concerns. We will determine whether the potentially significant human safety issue is inherent to implementation of the measure or is due to operator error prior to issuing any further IHAs to the Navy for pile driving activities in 2014 and beyond.

With regard to sound attenuation device implementation, we previously required the Navy to use such a device and to require that their contractors ensure: (1) that the device be capable of achieving attenuation performance of 10 dB of reduction and (2) that the device is properly deployed such that no reduction in performance may be attributable to operator error. However, because recent observations indicate that achievement of 10 dB of attenuation performance may not be reasonable, we now stipulate simply that the Navy must make the necessary contractual requirements to ensure that the device is capable of achieving optimal performance, and that deployment of the device is implemented properly such that no reduction in performance may be attributable to faulty deployment. Compliance with this stipulation is incumbent upon the Navy and it would not be appropriate for us to dictate the manner of compliance, including requirements for consultation with third parties.

Comment 4: The Commission recommends that we require the Navy to monitor the extent of the disturbance zone using additional shore- or vessel-based observers beyond the waterfront restricted area to (1) determine the numbers of marine mammals taken during pile driving and removal activities and (2) characterize the effects on those mammals.

Response: We believe that we have developed, in consultation with the Navy, a strategy that is appropriate to accomplish the stated objectives of the Commission's recommendation. The Commission states that the goal is not simply to employ a strategy that ensures monitoring out to a certain distance, but rather to employ a strategy that provides the information necessary to determine if the construction activities have adverse effects on marine mammals and to describe the nature and extent of those effects. We agree with that statement, and note that the Navy does not simply monitor within defined zones, ignoring occurrences outside those zones. The mitigation strategy is designed to implement shutdown of activity only for marine mammal occurrence within designated zones, but all observations of marine mammals and any observed behavior, whether construed as a reaction to project activity or not, are recorded regardless of distance to project activity. This information is coupled with the results of previous acoustic monitoring data (i.e., sound levels recorded at multiple defined distances from the activity) to draw conclusions about the impact of the activity on marine mammals. Importantly, the larger monitoring effort conducted by the Navy in deeper waters of Hood Canal during their 2011 project monitoring was an important piece of the Navy's overall monitoring strategy for the ongoing suite of actions at NBKB and may reasonably be used as a reference for the current activities. Using that information, as well as the results of required monitoring associated with the 2011–12 Test Pile Program, 2011–13 rehabilitation of the existing Explosives Handling Wharf, and the first year of construction for the EHW–2, we believe we have gained a sufficient understanding of marine mammal behavior in response to the specified activities, as well as occurrence and behavior within the Level B harassment zone in deeper waters beyond the waterfront restricted area, which is intensively monitored. We also note that the de facto zone of monitoring effort has been expanded for the duration of the concurrent barge mooring effort, as observers monitoring the waterfront at that location will also be collecting information on occurrence and potential reactions of marine mammals.

The Commission urges us to consider a more comprehensive approach to assessment of effects of activities co-located in time and space. We believe that the Navy has designed a comprehensive, multi-year approach for its monitoring strategy. It is not fiscally feasible, or the best use of resources, to deploy multiple vessel-based observers for year after year of similar activities. A strategic approach demands front-loaded effort that, when properly

designed, provides utility for subsequent years. Beginning in 2008, the Navy began to expand their efforts to better understand nature and frequency of occurrence for wildlife at NBKB. Opportunistic haul-out surveys and vessel-based wildlife surveys have been useful in evaluating the potential effects of construction activities. At the initiation of the recent construction activities, the Navy mounted an intensive monitoring effort, including deep-water monitoring (that was not mitigation-specific) and comprehensive acoustic monitoring, with the express purpose of providing a robust body of data that would form a reference for evaluation of future effects of similar activities. In addition, the Navy has proactively secured funding and sought collaboration with NMFS and other experts to conduct future surveys of Washington inland waters that will provide much-needed updates to our understanding of marine mammal abundance and distribution in the region.

Comment 5: The Commission recommends that we complete an analysis of the impact of the proposed activities together with the cumulative impacts of all the other pertinent risk factors (including but not limited to the Navy's concurrent barge mooring project) for marine mammals in the Hood Canal area.

Response: Section 101(a)(5)(D) of the MMPA requires NMFS to make a determination that the harassment incidental to a specified activity will have a negligible impact on the affected species or stocks of marine mammals, and will not result in an unmitigable adverse impact on the availability of marine mammals for taking for subsistence uses. Neither the MMPA nor NMFS' implementing regulations specify how to consider other activities and their impacts on the same populations. However, consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into the negligible impact analysis via their impacts on the environmental baseline (e.g., as reflected in the density/distribution and status of the species, population size and growth rate, and ambient noise).

In addition, cumulative effects were addressed in the Navy's Environmental Impact Statement and in the biological opinion prepared for this action, as well as in the NEPA analyses prepared for other actions conducted at the NBKB waterfront. These documents, as well as the relevant Stock Assessment Reports, are part of NMFS' Administrative Record for this action, and provided the decision-maker with information regarding other activities in the action area that affect marine mammals, an analysis of cumulative impacts, and other information relevant to the determination made under the MMPA.

Comment 6: The Commission recommends that we encourage the Navy to combine future requests for IHAs for all activities that would occur in the same general area and within the same year rather than segmenting those activities and their associated impacts by requesting separate authorizations.

Response: We agree with the Commission's recommendation and have encouraged the Navy to do so. However, we do not have the statutory authority to require the Navy to combine such requests. With our encouragement, the Navy is working to develop a regionally comprehensive approach to environmental compliance for reasonably foreseeable small actions, such as pile replacement and repair projects. A major project such as the current EHW–2 construction would likely remain as a standalone effort due to constraints related to planning, funding, and contracting.

Comment 7: The Commission recommends that we require the Navy to use the same data (e.g., source levels, sound attenuation factors, densities), methods, and justification for all pile driving and removal activities that occur during the same timeframe at NBKB.

Response: We concur with the Commission's recommendation and will require consistency from the Navy in future IHA requests. However, we are not overly concerned here because where there are inconsistencies they are due to use of conservative approaches. For example, in discussing source levels used for determining mitigation zones, the Commission notes that the Navy used a conservative estimate (i.e., the maximum source level) for the barge mooring project, but did not do so for the EHW–2. While the approach differs, conservatism is also built into the estimation of mitigation zones for EHW–2, not through use of a conservative source level, but by using the maximum radial distances to relevant thresholds, as measured during in site-specific acoustic monitoring. The modeled zones for the EHW–2 project were 22 and 5 m for the 180 and 190 dB zones, respectively, but the zones required of the Navy are 85 and 20 m, respectively. This more conservative approach was adopted at the urging and with the concurrence of the Commission in 2012. The Commission states that it is unclear why these inconsistencies are present, however, in each case the reason for the inconsistency and the rationale for our decision that use of an inconsistent approach is acceptable, if not desirable, is clearly presented in the associated FR notices.

Description of Marine Mammals in the Area of the Specified Activity

There are seven marine mammal species, four cetaceans and three pinnipeds, which may inhabit or transit through the waters nearby NBKB in the Hood Canal. These include the transient killer whale, harbor porpoise, Dall's porpoise, Steller sea lion, California sea lion, harbor seal, and humpback whale. The Steller sea lion and humpback whale are the only marine mammals that may occur within the Hood Canal that are listed under the Endangered Species Act (ESA); the humpback whale is listed as endangered and the eastern distinct population segment (DPS) of Steller sea lion is listed as threatened. The Steller sea lion is typically present in low numbers in the Hood Canal only from approximately October through mid-April. The humpback whale is not typically present in Hood Canal, with no confirmed sightings found in the literature or the Orca Network database (*http://www.orcanetwork.org/*) prior to January and February 2012, when one individual was observed repeatedly over a period of several weeks. No sightings have been recorded since that time and we consider the humpback whale to be a rare visitor to Hood Canal at most. While the southern resident killer whale is resident to the inland waters of Washington and British Columbia, it has not been observed in the Hood Canal in over 15 years. Therefore, these three stocks were excluded from further analysis. The FR notice (78 FR 29705; May 21, 2013) summarizes the population status and abundance of these species, and the Navy's application provides detailed life history information.

Potential Effects of the Specified Activity on Marine Mammals

We have determined that pile driving, as outlined in the project description, has the potential to result in behavioral harassment of marine mammals that may be present in the project vicinity while construction activity is being conducted. Pile driving could potentially harass those pinnipeds that are in the water close to the project site, whether exposed to airborne or underwater sound. The FR notice (78 FR 29705; May 21, 2013) provides a detailed description of marine mammal hearing and of the potential effects of

these construction activities on marine mammals.

Anticipated Effects on Habitat

The specified activities at NBKB will not result in permanent impacts to habitats used directly by marine mammals, such as haul-out sites, but may have potential short-term impacts to food sources such as forage fish and salmonids. There are no rookeries or major haul-out sites within 10 km (6.2 mi), foraging hotspots, or other ocean bottom structures of significant biological importance to marine mammals that may be present in the marine waters in the vicinity of the project area. Therefore, the main impact issue associated with the specified activity will be temporarily elevated sound levels and the associated direct effects on marine mammals, as discussed previously in this document. The most likely impact to marine mammal habitat occurs from pile driving effects on likely marine mammal prey (i.e., fish) near NBKB and minor impacts to the immediate substrate during construction activity associated with the EHW–2 project. The FR notice (78 FR 29705; May 21, 2013) describes these potential impacts in greater detail.

Summary of Previous Monitoring

The Navy complied with the mitigation and monitoring required under the previous authorization for this project. In accordance with the 2012 IHA, the Navy submitted a Year 1 Marine Mammal Monitoring Report (2012–2013), covering the period of July 16 through February 15. Due to delays in beginning the project the first day of monitored pile driving activity occurred on September 28, 2012, and a total of 78 days of pile driving occurred between then and February 14, 2013. That total included 56 days of vibratory driving only, three days of only impact driving, and 19 days where both vibratory and impact driving occurred. Marine mammal monitoring occurred the before, during, and after each pile driving event. During the course of these activities, the Navy did not exceed the take levels authorized under the IHA. For more detail, including full monitoring results and analysis, please see the monitoring report at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm*.

Mitigation

In order to issue an incidental take authorization (ITA) under Section 101(a)(5)(D) of the MMPA, we must, where applicable, set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant).

Measurements from similar pile driving events were coupled with practical spreading loss to estimate zones of influence (ZOIs; see ''Estimated Take by Incidental Harassment''); these values were used to develop mitigation measures for pile driving activities at NBKB. The ZOIs effectively represent the mitigation zones that will be established around each pile to prevent Level A harassment to marine mammals, while providing estimates of the areas within which Level B harassment might occur. In addition to the measures described later in this section, the Navy will employ the following standard mitigation measures:

(a) Conduct briefings between construction supervisors and crews, marine mammal monitoring team, acoustical monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

(b) Comply with applicable equipment sound standards and ensure that all construction equipment has sound control devices no less effective than those provided on the original equipment.

(c) For in-water heavy machinery work other than pile driving (using, e.g., standard barges, tug boats, barge-mounted excavators, or clamshell equipment used to place or remove material), if a marine mammal comes within 10 m, operations shall cease and vessels shall reduce speed to the minimum level required to maintain steerage and safe working conditions. This type of work could include the following activities: (1) movement of the barge to the pile location; (2) positioning of the pile on the substrate via a crane (i.e., stabbing the pile); (3) removal of the pile from the water column/substrate via a crane (i.e., deadpull); or (4) the placement of sound attenuation devices around the piles. For these activities, monitoring will take place from 15 minutes prior to initiation until the action is complete.

Monitoring and Shutdown for Pile Driving

The following measures will apply to the Navy's mitigation through shutdown and disturbance zones:

Shutdown Zone—For all pile driving and removal activities, the Navy will establish a shutdown zone intended to contain the area in which SPLs equal or exceed the 180/190 dB rms acoustic injury criteria. The purpose of a shutdown zone is to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area), thus preventing injury, serious injury, or death of marine mammals. Modeled distances for shutdown zones are shown in Table 2. However, during impact pile driving, the Navy would implement a minimum shutdown zone of 85 m radius for cetaceans and 20 m for pinnipeds around all pile driving activity. The modeled injury threshold distances are approximately 22 and 5 m, respectively, but the distances are increased based on in-situ recorded sound pressure levels from the TPP. During vibratory driving, the shutdown zone would be 10 m distance from the source for all animals. These precautionary measures are intended to act conservatively in the implementation of the measure and further reduce any possibility of acoustic injury, as well as to account for any undue reduction in the modeled zones stemming from the assumption of 10 dB attenuation from use of a bubble curtain.

Disturbance Zone—Disturbance zones are the areas in which SPLs equal or exceed 160 and 120 dB rms (for pulsed and non-pulsed sound, respectively). Disturbance zones provide utility for monitoring conducted for mitigation purposes (i.e., shutdown zone monitoring) by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring of disturbance zones enables observers to be aware of and communicate the presence of marine mammals in the project area but outside the shutdown zone and thus prepare for potential shutdowns of activity. However, the primary purpose of disturbance zone monitoring is for documenting incidents of Level B harassment; disturbance zone monitoring is discussed in greater detail later (see ''Monitoring and Reporting''). Nominal radial distances for disturbance zones are shown in Table 2. Given the size of the disturbance zone for vibratory pile driving, it is impossible to guarantee that all animals would be observed or to make comprehensive observations of fine-scale behavioral reactions to sound, and only a portion of the zone (e.g., what may be reasonably observed by visual observers stationed within the water

front restricted area [WRA]) will be monitored.

In order to document observed incidences of harassment, monitors record all marine mammal observations, regardless of location. The observer's location, as well as the location of the pile being driven, is known from a GPS. The location of the animal is estimated as a distance from the observer, which is then compared to the location from the pile. If acoustic monitoring is being conducted for that pile, a received SPL may be estimated, or the received level may be estimated on the basis of past or subsequent acoustic monitoring. It may then be determined whether the animal was exposed to sound levels constituting incidental harassment in post-processing of observational and acoustic data, and a precise accounting of observed incidences of harassment created. Therefore, although the predicted distances to behavioral harassment thresholds are useful for estimating incidental harassment for purposes of authorizing levels of incidental take, actual take may be determined in part through the use of empirical data. That information may then be used to extrapolate observed takes to reach an approximate understanding of actual total takes.

Monitoring Protocols—Monitoring would be conducted before, during, and after pile driving activities. In addition, observers shall record all incidences of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven. Observations made outside the shutdown zone will not result in shutdown; that pile segment would be completed without cessation, unless the animal approaches or enters the shutdown zone, at which point all pile driving activities will be halted. Monitoring will take place from 15 minutes prior to initiation through 15 minutes post-completion of pile driving activities. Pile driving activities include the time to remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes. Please see the Marine Mammal Monitoring Plan (available at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm*), developed by the Navy in agreement with us, for full details of the monitoring protocols.

The following additional measures apply to visual monitoring:

(1) Monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Qualified observers are trained biologists, with the following minimum qualifications:

- Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;
- Advanced education in biological science, wildlife management, mammalogy, or related fields (bachelor's degree or higher is required);
- Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

(2) Prior to the start of pile driving activity, the shutdown zone will be monitored for 15 minutes to ensure that it is clear of marine mammals. Pile driving will only commence once observers have declared the shutdown zone clear of marine mammals; animals will be allowed to remain in the shutdown zone (i.e., must leave of their own volition) and their behavior will be monitored and documented. The shutdown zone may only be declared clear, and pile driving started, when the entire shutdown zone is visible (i.e., when not obscured by dark, rain, fog, etc.). In addition, if such conditions should arise during impact pile driving that is already underway, the activity will be halted.

(3) If a marine mammal approaches or enters the shutdown zone during the course of pile driving operations, activity will be halted and delayed until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or 15 minutes have passed without re-detection of the animal. Monitoring will be conducted throughout the time required to drive a pile.

Sound Attenuation Devices

Bubble curtains shall be used during all impact pile driving. The device will distribute air bubbles around 100 percent of the piling perimeter for the full depth of the water column, and the lowest bubble ring shall be in contact with the mudline for the full circumference of the ring. Testing of the device by comparing attenuated and unattenuated strikes is not possible because of requirements in place to protect marbled murrelets (an ESA-listed bird species under the jurisdiction of the USFWS). However, in order to avoid loss of attenuation from design and implementation errors in the absence of such testing, a performance test of the device shall be conducted prior to initial use. The performance test shall confirm the calculated pressures and flow rates at each manifold ring. In addition, the contractor shall also train personnel in the proper balancing of air flow to the bubblers and shall submit an inspection/performance report to the Navy within 72 hours following the performance test.

Timing Restrictions

In Hood Canal, designated exist timing restrictions for pile driving activities to avoid in-water work when salmonids and other spawning forage fish are likely to be present. The in-water work window is July 16-February 15. The initial months (July to September) of the timing window overlap with times when Steller sea lions are not expected to be present within the project area. Until September 23, impact pile driving will only occur starting two hours after sunrise and ending two hours before sunset due to marbled murrelet nesting season. After September 23, in-water construction activities will occur during daylight hours (sunrise to sunset).

Soft Start

The use of a soft-start procedure is believed to provide additional protection to marine mammals by warning or providing a chance to leave the area prior to the hammer operating at full capacity, and typically involves a requirement to initiate sound from vibratory hammers for fifteen seconds at reduced energy followed by a 30-second waiting period. This procedure is repeated two additional times. However,

implementation of soft start for vibratory pile driving during previous pile driving work at NBKB has led to equipment failure and serious human safety concerns; those issues were detailed in the FR notice (78 FR 29705; May 21, 2013). Therefore, vibratory soft start is not required as a mitigation measure for this project, as we have determined it to not currently be practicable due to safety concerns. We have further determined this measure unnecessary to providing the means of effecting the least practicable impact on marine mammals and their habitat. For impact driving, soft start will be required, and contractors will provide an initial set of strikes from the impact hammer at reduced energy, followed by a 30-second waiting period, then two subsequent reduced energy strike sets. The reduced energy of an individual hammer cannot be quantified because of variation in individual drivers. The actual number of strikes at reduced energy will vary because operating the hammer at less than full power results in ''bouncing'' of the hammer as it strikes the pile, resulting in multiple ''strikes''. Soft start for impact driving will be required at the beginning of each day's pile driving work and at any time following a cessation of impact pile driving of 30 minutes or longer.

We have carefully evaluated the applicant's mitigation measures and considered a range of other measures in the context of ensuring that we prescribe the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another: (1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals; (2) the proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and (3) the practicability of the measure for applicant implementation, including consideration of personnel safety, and practicality of implementation.

Based on our evaluation of the applicant's planned measures, as well as any other potential measures that may be relevant to the specified activity, we have determined that these mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that we must, where applicable, set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the action area. Please see the Navy's Marine Mammal Monitoring Plan for full details of the requirements for monitoring and reporting.

Visual Marine Mammal Observations

The Navy will collect sighting data and behavioral responses to construction for marine mammal species observed in the region of activity during the period of activity. All observers will be trained in marine mammal identification and behaviors and are required to have no other construction-related tasks while conducting monitoring. The Navy will monitor the shutdown zone and disturbance zone before, during, and after pile driving, with observers located at the best practicable vantage points. Based on our requirements, the Marine Mammal Monitoring Plan would implement the following procedures for pile driving:

- MMOs would be located at the best vantage point(s) in order to properly see the entire shutdown zone and as much of the disturbance zone as possible.
- During all observation periods, observers will use binoculars and the naked eye to search continuously for marine mammals.
- If the shutdown zones are obscured by fog or poor lighting conditions, pile driving at that location will not be initiated until that zone is visible. Should such conditions arise while impact driving is underway, the activity would be halted.
- The shutdown and disturbance zones around the pile will be monitored for the presence of marine mammals before, during, and after any pile driving or removal activity.

Individuals implementing the monitoring protocol will assess its effectiveness using an adaptive approach. Monitoring biologists will use their best professional judgment throughout implementation and seek improvements to these methods when deemed appropriate. Any modifications to protocol will be coordinated between NMFS and the Navy.

Data Collection

We require that observers use approved data forms. Among other pieces of information, the Navy will record detailed information about any implementation of shutdowns, including the distance of animals to the pile and description of specific actions that ensued and resulting behavior of the animal, if any. In addition, the Navy will attempt to distinguish between the number of individual animals taken and the number of incidences of take. We require that, at a minimum, the following information be collected on the sighting forms:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Weather parameters (e.g., percent cover, visibility);
- Water conditions (e.g., sea state, tide state);
- Species, numbers, and, if possible, sex and age class of marine mammals;
- Description of any observable marine mammal behavior patterns, including bearing and direction of travel, and if possible, the correlation to SPLs;
- Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- Locations of all marine mammal observations; and
- Other human activity in the area.

Reporting

A draft report must be submitted to NMFS within 90 calendar days of the completion of the in-water work window. The report will include marine mammal observations pre-activity, during-activity, and post-activity during pile driving days, and will also provide descriptions of any problems encountered in deploying sound attenuating devices, any adverse responses to construction activities by marine mammals and a complete description of all mitigation shutdowns and the results of those actions and a refined take estimate based on the number of marine mammals observed during the course of construction. A final report must be submitted within 30 days following resolution of comments on the draft report.

Estimated Take by Incidental Harassment

With respect to the activities described here, the MMPA defines ''harassment'' as: ''Any act of pursuit,

torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].''

All anticipated takes will be by Level B harassment, involving temporary changes in behavior. The planned mitigation and monitoring measures are expected to minimize the possibility of injurious or lethal takes such that take by Level A harassment, serious injury or mortality is considered discountable. However, it is unlikely that injurious or lethal takes would occur even in the absence of the planned mitigation and monitoring measures.

If a marine mammal responds to a stimulus by changing its behavior (e.g., through relatively minor changes in locomotion direction/speed or vocalization behavior), the response may or may not constitute taking at the individual level, and is unlikely to affect the stock or the species as a whole. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on animals or on the stock or species could potentially be significant (Lusseau and Bejder, 2007; Weilgart, 2007). Given the many uncertainties in predicting the quantity and types of impacts of sound on marine mammals, it is common practice to estimate how many animals are likely to be present within a particular distance of a given activity, or exposed to a particular level of sound. This practice potentially overestimates the numbers of marine mammals taken. For example, during the past ten years, killer whales have been observed within the project area twice. On the basis of that information, an estimated amount of potential takes for killer whales is presented here. However, while a pod of killer whales could potentially visit again during the project timeframe, and thus be taken, it is more likely that they will not. Although incidental take of killer whales and Dall's porpoises was authorized for 2011–12 activities at NBKB on the basis of past observations of these species, no such takes were recorded and no individuals of these species were observed. Similarly, estimated actual take levels (observed takes extrapolated to the remainder of unobserved but ensonified area) were significantly less than authorized levels of take for the remaining species.

The project area is not believed to be particularly important habitat for marine mammals, nor is it considered an area frequented by marine mammals, although harbor seals are year-round residents of Hood Canal and sea lions are known to haul-out on submarines and other man-made objects at the NBKB waterfront (although typically at a distance of a mile or greater from the project site). Therefore, behavioral disturbances that could result from anthropogenic sound associated with these activities are expected to affect only a relatively small number of individual marine mammals, although those effects could be recurring over the life of the project if the same individuals remain in the project vicinity.

The Navy has requested authorization for the potential taking of small numbers of Steller sea lions, California sea lions, harbor seals, transient killer whales, Dall's porpoises, and harbor porpoises in the Hood Canal that may result from pile driving during construction activities associated with the wharf construction project described previously in this document.

Marine Mammal Densities

The Navy is in the process of developing, with input from regional marine mammal experts, estimates of marine mammal densities in Washington inland waters for the Navy Marine Species Density Database (NMSDD). A technical report will describe methodologies used to derive these densities, which are generally considered the best available information for Washington inland waters, except where specific local abundance information is available. Initial take estimates and impact assessment for the EHW–2 project relied on data available at the time the application was submitted, including survey efforts in the project area. For future projects at NBKB, it is likely that the NMSDD densities will be used in assessing project impacts. However, because the NMSDD report is not complete, and because use of the previous density or abundance information results in more conservative (i.e., higher) take estimates, the approach to take estimation used for the first year of EHW–2 construction is largely retained here. Please see Appendix A of the Navy's application for more information on the NMSDD information.

For all species, the most appropriate information available was used to estimate the number of potential incidences of take. For harbor seals, this involved published literature describing harbor seal research conducted in Washington and Oregon as well as more specific counts conducted in Hood Canal (Huber *et al.,* 2001; Jeffries *et al.,* 2003). Killer whales are known from two periods of occurrence (2003 and 2005) and are not known to preferentially use any specific portion of the Hood Canal. Therefore, density was calculated as the maximum number of individuals present at a given time during those occurrences (London, 2006), divided by the area of Hood Canal. The best information available for the remaining species in Hood Canal came from surveys conducted by the Navy at the NBKB waterfront or in the vicinity of the project area.

Beginning in April 2008, Navy personnel have recorded sightings of marine mammals occurring at known haul-outs along the NBKB waterfront, including docked submarines or other structures associated with NBKB docks and piers and the nearshore pontoons of the floating security fence. Sightings of marine mammals within the waters adjoining these locations were also recorded. Sightings were attempted whenever possible during a typical work week (i.e., Monday through Friday), but inclement weather, holidays, or security constraints often precluded surveys. These sightings took place frequently, although without a formal survey protocol. During the surveys, staff visited each of the above-mentioned locations and recorded observations of marine mammals. Surveys were conducted using binoculars and the naked eye from shoreline locations or the piers/wharves themselves. Because these surveys consist of opportunistic sighting data from shore-based observers, largely of hauled-out animals, there is no associated survey area appropriate for use in calculating a density from the abundance data. Data were compiled for the period from April 2008 through December 2012 for analysis here, and these data provide the basis for take estimation for Steller and California sea lions. Other information, including sightings data from other Navy survey efforts at NBKB, is available for these two species, but these data provide the most conservative (i.e., highest) local abundance estimates (and thus the highest estimates of potential take).

In addition, vessel-based marine wildlife surveys were conducted according to established survey protocols during July through September 2008 and November through May 2009–10 (Tannenbaum *et al.,* 2009, 2011). Eighteen complete surveys of the nearshore area resulted in observations of four marine mammal species (harbor seal, California sea lion, harbor porpoise, and Dall's porpoise). These surveys operated along pre-determined

transects parallel to the shoreline from the nearshore out to approximately 1,800 ft (549 m) from shoreline, at a spacing of 100 yd, and covered the entire NBKB waterfront (approximately 3.9 km^2 per survey) at a speed of 5 kn or less. Two observers recorded sightings of marine mammals both in the water and hauled out, including date, time, species, number of individuals, age (juvenile, adult), behavior (swimming, diving, hauled out, avoidance dive), and haul-out location. Positions of marine mammals were obtained by recording distance and bearing to the animal with a rangefinder and compass, noting the concurrent location of the boat with GPS, and, subsequently, analyzing these data to produce coordinates of the locations of all animals detected. These surveys resulted in the only observation of a Dall's porpoise near NBKB.

The Navy also conducted vessel-based line transect surveys in Hood Canal on non-construction days during the 2011 TPP in order to collect additional data for species present in Hood Canal. These surveys detected three marine mammal species (harbor seal, California sea lion, and harbor porpoise), and included surveys conducted in both the main body of Hood Canal, near the project area, and baseline surveys conducted for comparison in Dabob Bay, an area of Hood Canal that is not affected by sound from Navy actions at the NBKB waterfront. The surveys operated along pre-determined transects that followed a double saw-tooth pattern to achieve uniform coverage of the entire NBKB waterfront. The vessel traveled at a speed of approximately 5 kn when transiting along the transect lines. Two observers recorded sightings of marine mammals both in the water and hauled out, including the date, time, species, number of individuals, and behavior (swimming, diving, etc.). Positions of marine mammals were obtained by recording the distance and bearing to the animal(s), noting the concurrent location of the boat with GPS, and subsequently analyzing these data to produce coordinates of the locations of all animals detected. Sighting information for harbor porpoises was corrected for detectability ($g(0) = 0.54$; Barlow, 1988; Calambokidis *et al.,* 1993; Carretta *et al.,* 2001). Distance sampling methodologies were used to estimate densities of animals for the data. This information provides the best information for harbor porpoises.

The cetaceans, as well as the harbor seal, appear to range throughout Hood Canal; therefore, the analysis for this IHA assumes that harbor seal, transient killer whale, harbor porpoise, and Dall's porpoise are uniformly distributed in the project area. However, it should be noted that there have been no observations of cetaceans within the floating security barriers at NBKB; these barriers thus appear to effectively prevent cetaceans from approaching the shutdown zones. Although the Navy will implement a precautionary shutdown zone for cetaceans, anecdotal evidence suggests that cetaceans are not at risk of Level A harassment at NBKB even from louder activities (e.g., impact pile driving). The remaining species that occur in the project area, Steller sea lion and California sea lion, do not appear to utilize most of Hood Canal. The sea lions appear to be attracted to the man-made haul-out opportunities along the NBKB waterfront while dispersing for foraging opportunities elsewhere in Hood Canal. California sea lions were not reported during aerial surveys of Hood Canal (Jeffries *et al.,* 2000), and Steller sea lions have only been documented at the NBKB waterfront.

Description of Take Calculation

The take calculations presented here rely on the best data currently available for marine mammal populations in the Hood Canal. The methodology for estimating take was described in detail in the FR notice (78 FR 29705; May 21, 2013). The ZOI impact area is the estimated range of impact to the sound criteria. The distances specified in Table 2 were used to calculate ZOIs around each pile. All impact pile driving take calculations were based on the estimated threshold ranges assuming attenuation of 10 dB from use of a bubble curtain. The ZOI impact area took into consideration the possible affected area of the Hood Canal from the pile driving site furthest from shore with attenuation due to land shadowing from bends in the canal. Because of the close proximity of some of the piles to the shore, the narrowness of the canal at the project area, and the maximum fetch, the ZOIs for each threshold are not necessarily spherical and may be truncated.

While pile driving can occur any day throughout the in-water work window, and the analysis is conducted on a per day basis, only a fraction of that time (typically a matter of hours on any given day) is actually spent pile driving. Acoustic monitoring conducted as part of the TPP demonstrated that Level B harassment zones for vibratory pile driving are likely to be significantly smaller than the zones estimated through modeling based on measured source levels and practical spreading loss. Also of note is the fact that the effectiveness of mitigation measures in reducing takes is typically not quantified in the take estimation process. Here, we do explicitly account for an assumed level of efficacy for use of the bubble curtain, but not for the soft start associated with impact driving. In addition, equating exposure with response (i.e., a behavioral response meeting the definition of take under the MMPA) is simplistic and conservative assumption. For these reasons, these take estimates are likely to be conservative.

Airborne Sound—No incidents of incidental take resulting solely from airborne sound are likely, as distances to the harassment thresholds would not reach areas where pinnipeds may haul out. Harbor seals can haul out at a variety of natural or manmade locations, but the closest known harbor seal haul-out is at the Dosewallips River mouth (London, 2006) and Navy waterfront surveys and boat surveys have found it rare for harbor seals to haul out along the NBKB waterfront (Agness and Tannenbaum, 2009; Tannenbaum *et al.,* 2009, 2011; Navy, 2010). Individual seals have occasionally been observed hauled out on pontoons of the floating security fence within the restricted areas of NBKB, but this area is not with the airborne disturbance ZOI. Nearby piers are elevated well above the surface of the water and are inaccessible to pinnipeds, and seals have not been observed hauled out on the adjacent shoreline. Sea lions typically haul out on submarines docked at Delta Pier, approximately one mile from the project site.

We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with heads above water. However, these animals would previously have been 'taken' as a result of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Multiple incidents of exposure to sound above NMFS' thresholds for behavioral harassment are not believed to result in increased behavioral disturbance, in either nature or intensity of disturbance reaction. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted.

The derivation of density or abundance estimates for each species, as well as further description of the rationale for each take estimate, was described in detail in the FR notice (78 FR 29705; May 21, 2013). A summary of

the information and assumptions that went into take estimates for each species is provided here. Total take estimates are presented in Table 4.

• California sea lions—Data from waterfront surveys at NBKB was most appropriate, because haul-out opportunities provided by submarines at Delta Pier are the primary attractant for sea lions in the project vicinity and local abundances are higher than indicated by regional densities. In order to provide a margin of conservatism, the monthly averages for maximum daily numbers observed (in a given month) were used to estimate an average maximum daily abundance for the work window. Exposures were calculated assuming 31 individuals could be present, and therefore exposed to sound exceeding the behavioral harassment threshold, on each day of pile driving.

• Steller sea lions—The same data were used for Steller sea lions as for California sea lions, for the same reasons. Exposures were calculated assuming two individuals could be present, and therefore exposed to sound exceeding the behavioral harassment threshold, on each day of pile driving.

• Harbor seals—Data from Huber *et al.* (2001) and Jeffries *et al.* (2003) were used to produce a corrected instantaneous density for harbor seals in Hood Canal that accounts for animals in the water versus hauled out at any given time. Recently, the Navy discovered errors in those calculations (a smaller area was assumed for Hood Canal than was used in the initial surveys) that resulted in a higher density (1.31 vs. 1.06 animals/km^2). The earlier density was retained here as it provides a more conservative estimate of potential incidences of behavioral harassment.

• Killer whales—Regional density values produce an estimate of zero incidences of harassment. However, pods of transient killer whales have been observed in Hood Canal in 2003 and 2005, for a minimum of 59 days. In order to account for the possibility that killer whales could be present, we assume a pod size of six whales and a residence time of half the previous minimum (to account for likely avoidance of harassing stimuli) for estimating potential incidences of behavioral harassment (six individuals present for thirty days). We believe that this is likely a very conservative estimate.

• Dall's porpoise—Regional density values produce an estimate of zero incidences of harassment. However, a Dall's porpoise has been observed in waters off of NBKB, and the Navy has requested take authorization for this species. In order to account for possible presence of this species, and in the absence of information indicating any particular proportion of days, we assume that one porpoise could be present on each day of pile driving. This is not likely to be a very realistic estimate, as no Dall's porpoise has been observed in the past two years of monitoring at NBKB. It is, however, a reasonable compromise between the only available information and the Navy's request for take authorization.

• Harbor porpoise—Surveys from 2011 collected in waters off of NBKB provide the best data for this species. Preliminary results from those surveys indicated a density of 0.25 animals/km^2, and this value was used by the Navy in initial impact assessments. Additional data subsequently produced a revised density estimate of 0.149 animals/km^2; however, the Navy has requested that we retain the earlier value as it produces a more conservative estimate of potential incidences of behavioral harassment.

Potential takes could occur if individuals of these species are present in the vicinity when pile driving is occurring. Individuals that are taken could exhibit behavioral changes such as increased swimming speeds, increased surfacing time, or decreased foraging. Most likely, individuals may move away from the sound source and be temporarily displaced from the areas of pile driving. Potential takes by disturbance would likely have a negligible short-term effect on individuals and not result in population-level impacts.

TABLE 4—NUMBER OF POTENTIAL INCIDENTAL TAKES OF MARINE MAMMALS WITHIN VARIOUS ACOUSTIC THRESHOLD ZONES

Species	Density/ abundance	Underwater		Airborne	Total authorized takes
		Impact injury threshold [1]	Vibratory disturbance threshold (120 dB) [2]	Impact disturbance threshold [3]	
California sea lion	[4] 31.2	0	6,045	0	6,045
Steller sea lion	[4] 1.7	0	390	0	390
Harbor seal	1.31	0	10,530	0	10,530
Killer whale	[5] 0.0019	0	180	N/A	180
Dall's porpoise	[5] 0.000001	0	195	N/A	195
Harbor porpoise	0.250	0	1,950	N/A	1,950

[1] Acoustic injury threshold for impact pile driving is 190 dB for pinnipeds and 180 dB for cetaceans.

[2] The 160-dB acoustic harassment zone associated with impact pile driving would always be subsumed by the 120-dB harassment zone produced by vibratory driving. Therefore, takes are not calculated separately for the two zones.

[3] Acoustic disturbance threshold is 100 dB for sea lions and 90 dB for harbor seals. We do not believe that pinnipeds would be available for airborne acoustic harassment because they are not known to regularly haul-out at locations inside the zone in which airborne acoustic harassment could occur.

[4] Figures presented are abundance numbers, not density, and are calculated as the average of average daily maximum numbers per month. Abundance numbers are rounded to the nearest whole number for take estimation.

[5] Density values not used for take estimation. Assumptions are that a pod of six killer whales could be present for thirty days and that one Dall's porpoise could be present on each day of pile driving.

Negligible Impact and Small Numbers Analysis and Determinations

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' In making a negligible impact determination, NMFS considers a variety of factors, including but not limited to: (1) The number of anticipated mortalities; (2) the number and nature of anticipated injuries; (3) the number, nature, intensity, and duration of Level B harassment; and (4) the context in which the take occurs.

Small Numbers Analysis

The numbers of animals authorized to be taken for Steller and California sea lions and for Dall's porpoises would be considered small relative to the relevant stocks or populations (less than one percent for Steller sea lions and Dall's porpoise and less than three percent for California sea lions) even if each estimated taking occurred to a new individual—an extremely unlikely scenario. For pinnipeds occurring at the NBKB waterfront, there will almost certainly be some overlap in individuals present day-to-day and, for the Dall's porpoise, given the rare occurrence of this species in the Hood Canal it seems likely that for the number of takes contemplated here to occur, at least one to several individuals would have to remain in the area for an extended period of time. Further, for the pinniped species, these takes could potentially occur only within some small portion of the overall regional stock. For example, of the estimated 296,500 California sea lions, only certain adult and subadult males—believed to number approximately 3,000–5,000 by Jeffries *et al.* (2000)—travel north during the non-breeding season. That number has almost certainly increased with the population of California sea lions—the 2000 Stock Assessment Report for California sea lions reported an estimated population size of 204,000–214,000 animals—but likely remains a relatively small portion of the overall population.

For harbor seals, animals found in Hood Canal belong to a closed, resident population estimated at approximately 1,000 animals by Jeffries *et al.* (2003), and takes are likely to occur only within some portion of that closed population, rather than to animals from the Washington inland waters stock as a whole. The animals that are resident to Hood Canal, to which any incidental take would accrue, represent only seven percent of the best estimate of regional stock abundance. For transient killer whales, we estimate take based on an assumption that a single pod of whales, comprising six individuals, is present in the vicinity of the project area for the entire duration of the project. These six individuals represent a small number of transient killer whales, for which a conservative minimum estimate of 354 animals was given in the 2011 Stock Assessment Reports.

Little is known about harbor porpoise use of Hood Canal, and prior to monitoring associated with recent pile driving projects at NBKB, it was believed that harbor porpoises were infrequent visitors to the area. It is unclear from the limited information available what relationship harbor porpoise occurrence in Hood Canal may hold to the regional stock or whether similar usage of Hood Canal may be expected to be recurring. It is unknown how many unique individuals are represented by sightings in Hood Canal, although it is unlikely that these animals represent a large proportion of the overall stock. While we believe that the authorized numbers of incidental take would likely to occur to a much smaller number of individuals, the number of incidences of take relative to the stock abundance (approximately eighteen percent) remains within the bounds of what we consider to be small numbers.

As described in the FR notice (78 FR 29705; May 21, 2013) and summarized here, the estimated number of potential incidences of harassment for these species are likely much higher than will realistically occur. This is because (1) We use the maximum possible number of days (195) in estimating take, despite the fact that multiple delays and work stoppages are likely to result in a significantly lower number of actual pile driving days; (2) estimates for harbor porpoise and harbor seal rely on density estimates that are higher than what we consider to be the best available information; (3) sea lion estimates rely on the averaged maximum daily abundances per month, rather than simply an overall average which would provide a much lower abundance figure; and (4) the estimates for killer whale and Dall's porpoise use sparse information to attempt to account for the potential presence of species that have not been observed in Hood Canal since 2005 and 2008 (when a single individual was observed), respectively. In addition, with the exception of the bubble curtain, potential efficacy of mitigation measures in terms of reduction in numbers and/or intensity of incidences of take has not been quantified. Therefore, these take numbers are likely to be conservative.

Negligible Impact Analysis

Pile driving activities associated with the wharf construction project, as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment (behavioral disturbance) only, from airborne or underwater sounds generated from pile driving. Potential takes could occur if individuals of these species are present in the ensonified zone when pile driving is happening, which is likely to occur because (1) Harbor seals, which are frequently observed along the NBKB waterfront, are present within the WRA; (2) sea lions, which are less frequently observed, transit the WRA en route to haul-outs to the south at Delta Pier; or (3) cetaceans or pinnipeds transit the larger Level B harassment zone outside of the WRA.

No injury, serious injury, or mortality is anticipated given the methods of installation and measures designed to minimize the possibility of injury to marine mammals. The potential for these outcomes is minimized through the construction method and the implementation of the planned mitigation measures. Specifically, vibratory hammers will be the primary method of installation, and this activity does not have significant potential to cause injury to marine mammals due to the relatively low source levels produced (less than 190 dB) and the lack of potentially injurious source characteristics. Impact pile driving produces short, sharp pulses with higher peak levels and much sharper rise time to reach those peaks. When impact driving is necessary, required measures (use of a sound attenuation system, which reduces overall source levels as well as dampening the sharp, potentially injurious peaks, and implementation of shutdown zones) significantly reduce any possibility of injury. Likewise, Level B harassment will be reduced to the level of least practicable adverse impact through the use of mitigation measures described herein. that, given sufficient ''notice'' through mitigation measures including soft start (for impact driving), marine mammals are expected to move away from a sound source that is annoying prior to its becoming potentially injurious, and the likelihood that marine mammal detection ability by trained observers is high under the environmental conditions described for Hood Canal, enabling the implementation of shutdowns to avoid injury, serious injury, or mortality.

Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from past projects at NBKB, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. In response to vibratory driving, harbor seals (which may be somewhat habituated to human

activity along the NBKB waterfront) have been observed to orient towards and sometimes move towards the sound.

For pinnipeds, no rookeries are present in the project area, there are no haul-outs other than those provided opportunistically by man-made objects, and the project area is not known to provide foraging habitat of any special importance. No cetaceans are expected within the WRA. The pile driving activities analyzed here are similar to other nearby construction activities within the Hood Canal, including two recent projects conducted by the Navy at the same location (test pile project and EHW–1 pile replacement project) as well as work conducted in 2005 for the Hood Canal Bridge (SR–104) by the Washington Department of Transportation, which have taken place with no reported injuries or mortality to marine mammals, and no known long-term adverse consequences from behavioral harassment.

In summary, this negligible impact analysis is founded on the following factors: (1) The possibility of injury, serious injury, or mortality may reasonably be considered discountable; (2) the anticipated incidences of Level B harassment consist of, at worst, temporary modifications in behavior; (3) the absence of any major rookeries and only a few isolated and opportunistic haul-out areas near or adjacent to the project site; (4) the absence of cetaceans within the WRA and generally sporadic occurrence outside the WRA; (5) the absence of any other known areas or features of special significance for foraging or reproduction within the project area; (6) the presumed efficacy of the planned mitigation measures in reducing the effects of the specified activity to the level of least practicable impact. In addition, with the exception of the Steller sea lion (eastern DPS only), none of these stocks are listed under the ESA or considered of special status (e.g., depleted or strategic) under the MMPA. Five of the stocks for which take is authorized, including the Steller sea lion, are thought to be increasing. Insufficient information is available to determine population trends for the sixth stock (Dall's porpoise). In combination, we believe that these factors, as well as the available body of evidence from other similar activities, including those conducted at the same time of year and in the same location, demonstrate that the potential effects of the specified activity will have only short-term effects on individuals. The specified activity is not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.

Determinations

The number of marine mammals actually incidentally harassed by the project will depend on the distribution and abundance of marine mammals in the vicinity of the survey activity. However, we find that the number of potential takings authorized (by level B harassment only), which we consider to be a conservative, maximum estimate, is small relative to the relevant regional stock or population numbers, and that the effect of the activity will be mitigated to the level of least practicable impact through implementation of the mitigation and monitoring measures described previously. Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, we find that the total taking from the activity will have a negligible impact on the affected species or stocks.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

No tribal subsistence hunts are held in the vicinity of the project area; thus, temporary behavioral impacts to individual animals will not affect any subsistence activity. Further, no population or stock level impacts to marine mammals are anticipated or authorized. As a result, no impacts to the availability of the species or stock to the Pacific Northwest treaty tribes are expected as a result of the activities. Therefore, no relevant subsistence uses of marine mammals are implicated by this action.

Endangered Species Act (ESA)

There are two ESA-listed marine mammal species with known occurrence in the project area: the Eastern DPS of the Steller sea lion, listed as threatened, and the humpback whale, listed as endangered. Because of the potential presence of these species, the Navy engaged in a formal consultation with the NMFS Northwest Regional Office (NWR) under Section 7 of the ESA. We also initiated separate consultation with NWR because of our proposal to authorize the incidental take of Steller sea lions under the first IHA for EHW–2 construction. NWR's Biological Opinion, issued on September 29, 2011, concluded that the effects of pile driving activities at NBKB were likely to adversely affect, but not likely to jeopardize the continued existence of the eastern DPS of Steller sea lion. The Steller sea lion does not have critical habitat in the action area. Subsequent to the completion of the biological opinion, NWR prepared an Incidental Take Statement (ITS) to be appended to the opinion.

NWR compared the ITS, as well as the effects analysis and conclusions in the Biological Opinion, with the amount of and conditions on take proposed in the IHA and determined that the effects of issuing an IHA to the Navy for the taking of Steller sea lions incidental to construction activities are consistent with those described in the opinion. The September 29, 2011 Biological Opinion remains valid and the proposed MMPA authorization provided no new information about the effects of the action, nor did it change the extent of effects of the action, or any other basis to require reinitiation of the opinion. Therefore, the September 29, 2011 Biological Opinion meets the requirements of section 7(a)(2) of the ESA and implementing regulations at 50 CFR 402 for both the Navy construction action, as well as our action to issue an IHA under the MMPA, and no further consultation is required. NWR has issued a new ITS and appended it to the 2011 Biological Opinion upon issuance of the IHA.

National Environmental Policy Act (NEPA)

The Navy prepared an Environmental Impact Statement and issued a Record of Decision for this project. We acted as a cooperating agency in the preparation of that document, and reviewed the EIS and the public comments received and determined that preparation of additional NEPA analysis was not necessary. We subsequently adopted the Navy's EIS and issued our own Record of Decision for the issuance of the first IHA on July 6, 2012.

We reviewed the Navy's application for a renewed IHA for ongoing construction activities for 2013–14 and the 2012–13 monitoring report. Based on that review, we determined that the action follows closely the previous IHA and does not present any substantial changes, or significant new circumstances or information relevant to environmental concerns which would require preparation of a new or supplemental NEPA document. Therefore, we have determined that a new or supplemental Environmental Assessment or EIS is unnecessary, and, after review of public comments, reaffirm our 2012 ROD. The 2012 NEPA documents are available for review at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.*

Authorization

As a result of these determinations, we have issued an IHA to the Navy to conduct the described activities in the Hood Canal from the period of July 16, 2013, through February 15, 2014, provided the previously described mitigation, monitoring, and reporting requirements are incorporated.

Dated: July 11, 2013.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–17404 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC647

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to a Barge Mooring Project

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that we have issued an incidental harassment authorization (IHA) to the U.S. Navy (Navy) to incidentally harass, by Level B harassment only, four species of marine mammals during construction activities associated with a barge mooring project in Hood Canal, Washington.

DATES: This authorization is effective from July 16, 2013, through September 30, 2013.

ADDRESSES: A copy of the IHA and related documents may be obtained by visiting the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm* or by writing to Michael Payne, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East West Highway, Silver Spring, MD 20910. A memorandum describing our adoption of the Navy's Environmental Assessment (2013) and our associated Finding of No Significant Impact, prepared pursuant to the National Environmental Policy Act, are also available at the same site. Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the U.S. can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization. Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: ''Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].''

Summary of Request

We received an application on February 6, 2013, from the Navy for the taking of marine mammals incidental to pile driving and removal in association with a barge mooring project in the Hood Canal at Naval Base Kitsap in Bangor, WA (NBKB). The Navy submitted a revised version of the application on April 8, 2013, which we deemed adequate and complete. The barge mooring project is expected to require approximately eight weeks and will occur between July 16 and September 30, 2013. Four species of marine mammals are expected to be affected by the specified activities: California sea lion (*Zalophus californianus californianus*), harbor seal (*Phoca vitulina richardii*), harbor porpoise (*Phocoena phocoena vomerina*), and killer whale (transient only; *Orcinus orca*). These species may occur year-round in the Hood Canal, with the exception of the California sea lion, which is only present from late summer to late spring (August to early June).

NBKB provides berthing and support services to Navy submarines and other fleet assets. Commander Submarine Development Squadron Five (CSDS–5) is a tenant command on NBKB and is the working repository for deep ocean technology and operational, at-sea application of that technology. CSDS–5 currently moors and operates a research barge at the Service Pier on NBKB and plans to install mooring for a new larger research barge equipped with upgraded technology necessary for continuing the Navy mission. CSDS–5 currently conducts research equipment operations from an existing 115-ft by 35-ft barge with a 4-ft draft that was constructed in 1940 and cannot accommodate the new research equipment. A new larger barge measuring 260 ft by 85 ft with a 10-ft draft will replace the existing barge. Activities associated with the project include the removal of an existing mooring dolphin, the relocation and addition of floating pier sections, and the installation of up to twenty steel piles to support the barge, electrical transformer platform, and relocated pier sections (see Figures 1–2 and 1–3 in the Navy's application). All steel piles will be driven with a vibratory hammer for their initial embedment depths and may be finished with an impact hammer for proofing, as necessary. Proofing involves striking a driven pile with an impact hammer to verify that it provides the required load-bearing capacity, as indicated by the number of hammer blows per foot of pile advancement. Sound attenuation measures (i.e.,

bubble curtain) will be used during all impact hammer operations.

For pile driving activities, the Navy used thresholds recommended by NMFS for assessing project impacts, outlined later in this document. The Navy assumed practical spreading loss and used empirically-measured source levels from a similar project conducted at NBKB to estimate potential marine mammal exposures. Predicted exposures are outlined later in this document. The calculations predict that only Level B harassments will occur associated with pile driving or construction activities.

Description of the Specified Activity

NBKB is located on the Hood Canal approximately twenty miles (32 km) west of Seattle, Washington (see Figures 1–1 and 2–1 in the Navy's application). The specified actions with the potential to cause harassment of marine mammals within the waterways adjacent to NBKB, under the MMPA, are vibratory and impact pile driving and removal of piles via vibratory driver associated with the barge mooring project. All in-water construction activities within the Hood Canal are only permitted during July 16–February 15 in order to protect spawning fish populations; however, the entire barge mooring project is scheduled to be completed by September 30, 2013. Additional details regarding the specified geographic area and construction plans for the project were described in our **Federal Register** notice of proposed authorization (78 FR 30273; May 22, 2013; hereafter, the FR notice); please see that document or the Navy's application for more information.

The project consists of three components: The relocation and addition to the Port Operations pier, the removal of existing infrastructure, and the installation of the CSDS–5 research barge mooring piles. The barge mooring project is expected to require approximately forty work days and will occur only between July 16 and September 30, 2013. Figures 2–2 and 2–3 of the Navy's application contain details of the project area and site plan. The project is expected to require the installation of sixteen hollow steel pipe piles, including four 20-in diameter piles, three 24-in diameter piles, five 36-in diameter piles, and four 48-in diameter piles. Although only four 48-in piles are expected to be necessary, we include an additional four 48-in piles (for a total of eight 48-in piles and twenty total piles) in the effects analysis in the event that contingency piles are required. The 48-in piles will be the primary mooring supports for the new barge. In addition, one 24-in diameter pile will be removed using vibratory pile driving equipment.

The Navy expects that a maximum of four piles can be driven per day, although this total is unlikely to be reached due to various delays that may be expected during construction work. The total number of days for both extraction and installation are not likely to exceed twenty workdays. Piles will be installed using mainly vibratory pile driving, although some piles may require impact driving to ensure load bearing capacity (proofing) or if substrate conditions do not allow the pile to reach the specified tip elevation with a vibratory driver. When the impact driver is required, the Navy expects that 500 strikes will be necessary per pile, resulting in approximately 2,000 strikes per day under the maximum scenario. All piles driven with an impact hammer will be surrounded by a bubble curtain over the full water column to minimize in-water noise.

Description of Sound Sources and Distances to Thresholds

An in-depth description of sound sources in general was provided in the FR notice (78 FR 30273; May 22, 2013). Significant sound-producing in-water construction activities associated with the project include impact and vibratory pile driving.

NMFS uses generic sound exposure thresholds to determine when an activity that produces sound might result in impacts to a marine mammal such that a take by harassment might occur. To date, no studies have been conducted that examine impacts to marine mammals from pile driving sounds from which empirical sound thresholds have been established. Current NMFS practice (in relation to the MMPA) regarding exposure of marine mammals to sound is that cetaceans and pinnipeds exposed to sound levels of 180 and 190 dB root mean square (rms; note that all underwater sound levels in this document are referenced to a pressure of 1 μPa) or above, respectively, are considered to have been taken by Level A (i.e., injurious) harassment, while behavioral harassment (Level B) is considered to have occurred when marine mammals are exposed to sounds at or above 120 dB rms for continuous sound (such as will be produced by vibratory pile driving) and 160 dB rms for pulsed sound (produced by impact pile driving), but below injurious thresholds. For airborne sound, pinniped disturbance from haul-outs has been documented at 100 dB (unweighted) for pinnipeds in general, and at 90 dB (unweighted) for harbor seals (note that all airborne sound levels in this document are referenced to a pressure of 20 μPa). NMFS uses these levels as guidelines to estimate when harassment may occur. NMFS is currently revising these acoustic guidelines. For more information on that process, please visit *http://www.nmfs.noaa.gov/pr/acoustics/guidelines.htm.*

Sound levels can be greatly reduced during impact pile driving using sound attenuation devices. The Navy is required to use sound attenuation devices for all impact pile driving, and has elected to use bubble curtains. Bubble curtains work by creating a column of air bubbles rising around a pile from the substrate to the water surface. The air bubbles absorb and scatter sound waves emanating from the pile, thereby reducing the sound energy. A confined bubble curtain contains the air bubbles within a flexible or rigid sleeve made from plastic, cloth, or pipe. Confined bubble curtains generally offer higher attenuation levels than unconfined curtains because they may physically block sound waves and they prevent air bubbles from migrating away from the pile.

The literature presents a wide array of observed attenuation results for bubble curtains (e.g., Oestman *et al.,* 2009, Coleman, 2011, Caltrans, 2012). The variability in attenuation levels is due to variation in design, as well as differences in site conditions and difficulty in properly installing and operating in-water attenuation devices. As a general rule, reductions of greater than 10 dB cannot be reliably predicted. On the basis of existing data regarding bubble curtain efficacy, as well as site-specific measurements from the Navy's 2011 Test Pile Project (TPP; Illingworth & Rodkin, Inc., 2012), we have determined that 8 dB is a reasonable assumption regarding average SPL (rms) reduction. To avoid loss of attenuation from design and implementation errors, the Navy has required specific bubble curtain design specifications, including testing requirements for air pressure and flow prior to initial impact hammer use, and a requirement for placement on the substrate.

Distance to Sound Thresholds

Pile driving generates underwater noise that can potentially result in disturbance to marine mammals in the project area. Please see the FR notice (78 FR 30273; May 22, 2013) for a detailed description of the calculations and information used to estimate distances to relevant threshold levels.

Transmission loss, or the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source, was estimated as so-called ''practical spreading loss.'' This model follows a geometric propagation loss based on the distance from the pile, resulting in a 4.5 dB reduction in level for each doubling of distance from the source. In the model used here, the sound pressure level (SPL) at some distance away from the source (e.g., driven pile) is governed by a measured source level, minus the transmission loss of the energy as it dissipates with distance.

The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. The Navy previously conducted measurements for driving of steel piles at NBKB as part of the TPP (Illingworth & Rodkin, Inc., 2012), and we have determined that use of those values is appropriate to determine reasonable SPLs and their associated effects on marine mammals that are likely to result from pile driving at NBKB. During the TPP, SPLs from driving of 24-, 36-, and 48-in piles by impact and vibratory hammers were measured. Because 20-in piles were not measured during the TPP, we use sound pressure levels from the 24-in piles as a conservative estimate. Sound levels associated with vibratory pile removal are assumed to be the same as those during vibratory installation (Reyff, 2007)—which is likely a conservative assumption—and have been taken into consideration in the modeling analysis.

Representative data for pile driving SPLs recorded from the TPP were presented in the FR notice (78 FR 30273; May 22, 2013). Because it is unknown what size pile may be driven on any given day, the most conservative values (i.e., highest) were used, with practical spreading loss, to estimate distances to relevant thresholds. For impact pile driving, distances to the marine mammal sound thresholds were calculated with the assumption of an 8 dB reduction in source levels from the use of a bubble curtain. Source values (at 10 m) used for calculations were 188 dB for impact driving (196 dB as a representative value, less 8 dB of sound attenuation from use of a bubble curtain) and 172 dB for vibratory driving. For airborne sound during the TPP, vibratory driving was measured at 102 dB and impact driving at 109 dB (both at 15 m). These values were used, with spherical spreading loss, to estimate distances to relevant thresholds. All calculated distances to and the total area encompassed by the marine mammal sound thresholds are provided in Tables 1 and 2. Predicted distances to thresholds for different sources are shown in Figures 6–1 through 6–4 of the Navy's application.

TABLE 1—DISTANCES TO RELEVANT SOUND THRESHOLDS AND AREAS OF ENSONIFICATION

Description	Effective source level (dB at 10 m)	Distance to threshold (m) and associated area of ensonification (km^2)			
		190 dB	180 dB	160 dB	120 dB
Steel piles, impact	188	7, 0.0002	34, 0.0036	736, 1.702	n/a
Steel piles, vibratory	172	1, <0.0001	3, <0.0001	n/a	[1] 29,286, 16.1

[1] This distance cannot actually be attained at the project location. The area presented is actual.

TABLE 2—DISTANCES TO RELEVANT SOUND THRESHOLDS AND AREAS OF ENSONIFICATION, AIRBORNE SOUND

Group	Threshold, re 20 μPa rms (unweighted)	Distance to threshold (m) and associated area of ensonification (km^2)	
		Impact driving	Vibratory driving
Harbor seals	90 dB	134, 0.0564	60, 0.0113
California sea lions	100 dB	42, 0.0055	19, 0.0011

There are no haul-out locations within the airborne harassment zones, which are encompassed by the zones estimated for underwater sound. Protective measures will be in place out to the distances calculated for the underwater thresholds, and the distances for the airborne thresholds will be covered fully by mitigation and monitoring measures in place for underwater sound thresholds. We recognize that pinnipeds in water that are within the area of ensonification for airborne sound could be incidentally taken by either underwater or airborne sound or both. We consider these incidences of harassment to be accounted for in the take estimates for underwater sound.

Comments and Responses

We published a notice of receipt of the Navy's application and proposed IHA in the **Federal Register** on May 22, 2013 (78 FR 30273). NMFS received comments from the Marine Mammal Commission (Commission). The Commission's comments and our responses are provided here, and the comments have been posted on the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.*

Comment 1: The Commission recommends that we require the Navy to re-estimate the number of harbor seal takes using more recent survey data from Tannenbaum *et al.* (2009, 2011), which is based on the total estimated population, rather than the Navy's methodology of reducing the density for the proportion of seals hauled out and older data.

Response: As described in greater detail in the FR notice, there are two sources of information from which a suitable density estimate may be derived for harbor seals. These include aerial surveys of Hood Canal (358.4 km^2) conducted in 1999 and vessel-based marine wildlife surveys conducted by the Navy in nearshore waters of NBKB (3.9 km^2) during July through September 2008 and November through May 2009–10. Despite the time lapse, these survey efforts produce comparable results. Because harbor seals, unlike sea lions, form a resident population in Hood Canal and are not known to be attracted to the NBKB waterfront by any foraging or haul-out

opportunity, it is the opinion of both NMFS and the Navy that it is preferable to use the density value that is derived from a survey of the entire population. The Tannenbaum *et al.* (2009, 2011) data are not based on the total estimated population, but on surveys of a very small section of Hood Canal (approximately one percent of the Hood Canal area along the NBKB waterfront).

Based on the 1999 surveys, which also form the basis for the most recent abundance estimates provided in NMFS' Stock Assessment Report for the Washington inland waters stock of harbor seals, Jeffries *et al.* (2003) estimated the abundance of harbor seals in the Hood Canal as 1,088 individuals. The resulting density is 3.04 animals/km^2; however, use of this density in estimating take would make the assumption that 100 percent of the animals would be in the water at all times. Therefore, a factor derived from Huber *et al.* (2001)—only 35 percent of seals are in the water at any given time—was applied to correct for animals out of the water and not available to be exposed to underwater sound; the resulting corrected density of seals in the water at any given time is 1.06 animals/km^2.

The Commission disagrees with this approach because of their contention that (1) an instantaneous estimate of animals in the water at a given time does not produce an accurate assessment of the number of individuals that may enter the water over the daily duration of the activity and (2) use of the uncorrected density would be consistent with our decision to base the number of takes of sea lions on average monthly maximum abundance estimates at NBKB haul-out sites, under the assumption that each individual present would enter the water and therefore be exposed to underwater sound that may result in behavioral harassment at some point on any given day. With regard to the second point, we note that consistency between approaches for sea lions and for harbor seals would not be appropriate. Sea lions are attracted to the NBKB waterfront by the presence of submarines and other haul-out opportunities. Site-specific data therefore better reflects the nature of sea lion occurrence than does a regional density.

With regard to the first point, as acknowledged in the FR notice (78 FR 30273; May 22, 2013), we recognize that over the course of a day, while the proportion of animals in the water may not vary significantly, different individuals may enter and exit the water. That is, it is probable that greater than 35 percent of seals will enter the water at some point during the day. No data exist regarding fine-scale harbor seal movements within the project area on time durations of less than a day, thus precluding an assessment of ingress or egress of different animals through the action area. As such, it is impossible, given available data, to determine exactly what number of individuals above 35 percent may potentially be exposed to underwater sound. Therefore, we are left to make a decision, on the basis of limited available information, regarding which of these two scenarios (i.e., 100 percent vs. 35 percent of harbor seals are in the water and exposed to sound) produces a more accurate estimate of the potential incidents of take.

First, we understand that hauled-out harbor seals are necessarily at haul-outs. No significant harbor seal haul-outs are located within or near the action area. Harbor seals observed in the vicinity of the NBKB shoreline are rarely hauled-out (for example, in formal surveys during 2007–08, approximately 86 percent of observed seals were swimming), and when hauled-out, they do so opportunistically (i.e., on floating booms rather than established haul-outs). Harbor seals are typically unsuited for using manmade haul-outs at NBKB, which are used by sea lions. Primary harbor seal haul-outs in Hood Canal are located at significant distance (20 km or more) from the action area in Dabob Bay or further south (see Figure 4–1 in the Navy's application), meaning that animals casually entering the water from haul-outs or flushing due to some disturbance at those locations would not be exposed to underwater sound from the project; rather, only those animals embarking on foraging trips and entering the action area may be exposed.

Second, we know that harbor seals in Hood Canal are not likely to have a uniform distribution as is assumed through use of a density estimate, but are likely to be relatively concentrated near areas of interest such as the haul-outs found in Dabob Bay or foraging areas. The majority of the action area consists of the Level B harassment zone in deeper waters of Hood Canal; past observations from surveys and required monitoring have confirmed that harbor seals are less abundant in these waters.

Third, a typical pile driving day (in terms of the actual time spent driving) is much shorter than the 8–15 hours cited by the Commission as a representative pile driving day. Construction scheduling and notional production rates in concert with typical delays mean that hammers are active for only some small fraction of time on pile driving ''days''. For example, during the first year of construction for the second explosives handling wharf (EHW–2; a separate action occurring at NBKB), vibratory pile driving occurred on 75 days, but only for an approximate total time of 71 hours.

What we know tells us that (1) The turnover of harbor seals (in and out of the water) is occurring primarily outside the action area and would not be expected to result in a greater number of individuals entering the action area within a given day and being harassed than is assumed; (2) there are likely to be significantly fewer harbor seals in the majority of the action area than would be indicated by the uncorrected density; and (3) pile driving actually occurs over a limited timeframe on any given day, reducing the amount of time over which new individuals might enter the action area within a given day. These factors lead us to believe that the corrected density is likely to more closely approximate the number of seals that may be found in the action area than does the uncorrected density, and there are no existing data that would indicate that the proportion of individuals entering the water within the predicted area of effect during pile driving would be dramatically larger than 35 percent. Therefore, the Commission's suggestion that 100 percent of the population be used to estimate density would likely result in a gross exaggeration of potential take. Moreover, because the Navy is typically unable to determine from field observations whether the same or different individuals are being exposed, each observation is recorded as a new take, although an individual theoretically would only be considered as taken once in a given day.

Finally, we note that during the course of four previous IHAs over two years (2011–12), the Navy has been authorized for 6,725 incidents of incidental harassment (corrected for actual number of pile driving days). The total estimate of actual incidents of take (observed takes and observations extrapolated to unobserved area) was 868. This is almost certainly negatively biased, but the huge disparity does provide confirmation that we are not significantly underestimating takes.

Comment 2: The Commission recommends that we require the Navy to implement soft start procedures after 15 minutes if pile driving or removal is delayed or shut down because of the presence of a marine mammal within or approaching the shutdown zone.

Response: We do not believe the recommendation would be effective in reducing the number or intensity of incidents of harassment—in fact, we believe that implementation of this

recommendation may actually increase the number of incidents of harassment by extending the overall project duration—while imposing a high cost in terms of operational practicability. We note here that, while the Commission recommends use of the measure to avoid serious injury (i.e., injury that will result in death of the animal), such an outcome is extremely unlikely even in the absence of any mitigation measures (as described in the FR notice at 78 FR 30273; May 22, 2013). Given that conclusion, we address our response to the potential usefulness of the measure in avoidance of non-serious injury (i.e., Level A harassment).

Soft start is required for the first impact pile driving of each day and, subsequently, after any impact pile driving stoppage of 30 minutes or greater. The purpose of a soft start is to provide a ''warning'' to animals by initiating the production of underwater sound at lower levels than are produced at full operating power. This warning is presumed to allow animals the opportunity to move away from an unpleasant stimulus and to potentially reduce the intensity of behavioral reactions to noise or prevent injury of animals that may remain undetected in the zone ensonified to potentially injurious levels. However, soft start requires additional time, resulting in a larger temporal footprint for the project. That is, soft start requires a longer cumulative period of pile driving (i.e., hours) but, more importantly, leads to a longer overall duration (i.e., more days on which pile driving occurs). In order to maximize the effectiveness of soft start while minimizing the implementation costs, we require soft start after a period of extended and unobserved relative silence (i.e., at the beginning of the day, after the end of the required 30-minute post-activity monitoring period, or after 30 minutes with no impact driving). It is after these periods that marine mammals are more likely to closely approach the site (because it is relatively quiet) and less likely to be observed prior to initiation of the activity (because continuous monitoring has been interrupted).

The Commission justifies this recommendation on the basis of the potential for undetected animals to remain in the shutdown zone, and describes various biases (i.e., availability, detection, and perception) on an observer's ability to detect an animal. We do not believe that time is a factor in determining the influence of these biases on the probability of observing an animal in the shutdown zone. That is, an observer is not more likely to detect the presence of an animal at the 15-minute mark of continuous monitoring than after 30 minutes (it is established that soft start is required after any unmonitored period). Therefore, requiring soft start after 15 minutes (i.e., more soft starts) is not likely to result in increased avoidance of injury. Finally, we do not believe that the use of soft start may be expected to appreciably reduce the potential for injury where the probability of detection is high (e.g., small, shallow zones with good environmental conditions). Rather, the primary purpose of soft start under such conditions is to reduce the intensity of potential behavioral reactions to underwater sound in the disturbance zone.

As noted by the Commission, there are multiple reasons why marine mammals may remain in a shutdown zone and yet be undetected by observers. Animals are missed because they are underwater (availability bias) or because they are available to be seen, but are missed by observers (perception and detection biases) (e.g., Marsh and Sinclair, 1989). Negative bias on perception or detection of an available animal may result from environmental conditions, limitations inherent to the observation platform, or observer ability. While missed detections are possible in theory, this would require that an animal would either (a) remain submerged (i.e., be unavailable) for periods of time approaching or exceeding 15 minutes and/or (b) remain undetected while at the surface. We provide further site-specific detail below.

First, environmental conditions in the Hood Canal are typically excellent and, unlike the moving aerial or vessel-based observation platforms for which detectability bias is often a concern, the observers here will be positioned in the most suitable locations to ensure high detectability (randomness of observations is not a concern, as it is for abundance sampling). We believe that the probability of detecting animals within the shutdown zones proposed for this action approaches 100 percent. The shutdown zones are small, with radial distances of only 10 m and 36 m for the 190- and 180-dB zones, respectively, while the 180 dB zone for cetaceans is notional only—no cetaceans have ever been recorded as entering the security area bounded by the floating port security barrier. Regarding availability, the most abundant species, and therefore the species most likely to be present in the mitigation zones, are the harbor seal and California sea lion.

It is generally unlikely that a pinniped would remain within 10 m of an active construction zone, in the absence of any known foraging opportunities or other attractant of any significance, for an extended period of time. However, some harbor seals have been known to frequent the areas surrounding existing wharves at NBKB. Even when this situation does occur, the possibility that individuals would remain submerged for a period of time exceeding 15 minutes is discountable.

Dive behavior for harbor seals, including typical duration, is influenced by a variety of factors, such as behavioral context, local bathymetric conditions, and the specific physiological characteristics of the animal (e.g., Harkonen, 1987a,b; Eguchi and Harvey, 2005). Dive depth may be expected to correlate well with dive duration. However, Eguchi and Harvey (2005) showed that average dive durations in Monterey Bay, where available depths are much deeper than those in the nearshore environment at NBKB, were only 4.8 and 5.5 minutes for females and males, respectively. Although fine-scale population structure exists for harbor seals on a geographic basis from California to Alaska (Carretta *et al.,* 2011), similar results have been obtained in Alaska and Washington. Dive durations for harbor seals from three locations across the Gulf of Alaska were typically less than 4 minutes across factors (Hastings *et al.,* 2004). Closer to the action area in Puget Sound waters, Suryan and Harvey (1998) reported dive depths ranging from 3.2–4.6 min. Importantly, those durations were reduced in nearshore waters similar to those in the shutdown zone (1.5–3.6 min). Conversely, dive durations were somewhat longer during milling behavior, which is sometimes observed in the action area. However, surface intervals (which ranged from 0.6–0.9 min) showed a significantly positive correlation to dive duration (Suryan and Harvey, 1998), meaning that longer dives, or periods of high availability bias, are followed by periods of relatively greater availability.

Sea lions employ a shallow epipelagic foraging strategy, and numerous studies have reported mean dive times of approximately 2 minutes for California sea lions (e.g., Feldkamp *et al.,* 1989 [mean dive time less than 3 min]; Weise *et al.,* 2006 [mean dive time 1.9±1.6 min]). Kuhn *et al.* (2003) cite published values for sea lion aerobic dive limits ranging from 2.3–5.8 minutes and, while it is possible that sea lions may dive beyond these limits when foraging on the benthos, significantly longer dive durations would not be expected in shallow waters. In addition, while short surface intervals are also possible,

longer values are typical of data found in the literature for animals engaged in foraging (e.g., Costa *et al.* (2007) report a mean surface interval of 1.6 minutes). Sea lions will typically spend a much greater proportion of time at the surface when not foraging, and behavioral observations in the nearshore action area show that California sea lions are typically traveling, likely to haul-out opportunities at Delta Pier.

Under the typically excellent observation conditions found in the Hood Canal, we believe that surfaced animals would be observed. Based on the foregoing factors, we have high confidence in the ability of observers to detect marine mammals in the shutdown zones estimated for this project in the Hood Canal.

Comment 3: The Commission recommends that we require the Navy to consult with the Washington State Department of Transportation and/or the California Department of Transportation to (1) determine whether soft start procedures can be used safely with the vibratory hammers that the Navy plans to use prior to eliminating the Navy's requirement to implement those measures and (2) clarify and troubleshoot the sound attenuation device implementation procedures to ensure the device's efficacy.

Response: We concur with the first part of the Commission's recommendation and will facilitate the suggested consultation. However, this cannot be accomplished prior to issuance of the IHA due to the Navy's operational needs. Accordingly, we deem vibratory soft starts to not currently be practicable due to safety concerns. We will determine whether the potentially significant human safety issue is inherent to implementation of the measure or is due to operator error prior to issuing any further IHAs to the Navy for pile driving activities in 2014 and beyond.

With regard to sound attenuation device implementation, we previously required the Navy to use such a device and to require that their contractors ensure: (1) That the device be capable of achieving attenuation performance of 10 dB of reduction and (2) that the device is properly deployed such that no reduction in performance may be attributable to operator error. However, because recent observations indicate that achievement of 10 dB of attenuation performance may not be reasonable, we now stipulate simply that the Navy must make the necessary contractual requirements to ensure that the device is capable of achieving optimal performance, and that deployment of the device is implemented properly such that no reduction in performance may be attributable to faulty deployment. Compliance with this stipulation is incumbent upon the Navy and it would not be appropriate for us to dictate the manner of compliance, including requirements for consultation with third parties.

Comment 4: The Commission recommends that we require the Navy to monitor the extent of the disturbance zone using additional shore- or vessel-based observers throughout Hood Canal to (1) determine the numbers of marine mammals taken during pile driving and removal activities and (2) characterize the effects on those mammals.

Response: We believe that we have developed, in consultation with the Navy, a strategy that is appropriate to accomplish the stated objectives of the Commission's recommendation. The Commission states that the goal is not simply to employ a strategy that ensures monitoring out to a certain distance, but rather to employ a strategy that provides the information necessary to determine if the construction activities have adverse effects on marine mammals and to describe the nature and extent of those effects. We agree with that statement, and note that the Navy does not simply monitor within defined zones, ignoring occurrences outside those zones. The mitigation strategy is designed to implement shutdown of activity only for marine mammal occurrence within designated zones, but all observations of marine mammals and any observed behavior, whether construed as a reaction to project activity or not, are recorded regardless of distance to project activity. This information is coupled with the results of previous acoustic monitoring data (i.e., sound levels recorded at multiple defined distances from the activity) to draw conclusions about the impact of the activity on marine mammals. Importantly, the larger monitoring effort conducted by the Navy in deeper waters of Hood Canal during their 2011 project monitoring was an important piece of the Navy's overall monitoring strategy for the ongoing suite of actions at NBKB and may reasonably be used as a reference for the current activities. Using that information, as well as the results of required monitoring associated with the 2011–12 Test Pile Program, 2011–13 rehabilitation of the existing Explosives Handling Wharf, and the first year of construction for the EHW–2, we believe we have gained an acceptable understanding of marine mammal behavior in response to the specified activities, as well as occurrence and behavior within the Level B harassment zone in deeper waters beyond the waterfront restricted area, which is intensively monitored. We also note that the de facto zone of monitoring effort has been expanded for this project, as observers monitoring the concurrent EHW–2 project will also be collecting information on occurrence and potential reactions of marine mammals.

The Commission urges us to consider a more comprehensive approach to assessment of effects of activities co-located in time and space. We believe that the Navy has designed a comprehensive, multi-year approach for its monitoring strategy. It is not fiscally feasible, or the best use of resources, to deploy multiple vessel-based observers for year after year of similar activities. A strategic approach demands front-loaded effort that, when properly designed, provides utility for subsequent years. Beginning in 2008, the Navy began to expand their efforts to better understand nature and frequency of occurrence for wildlife at NBKB. Opportunistic haul-out surveys and vessel-based wildlife surveys have been useful in evaluating the potential effects of construction activities. At the initiation of the recent construction activities, the Navy mounted an intensive monitoring effort, including deep-water monitoring that was not mitigation-specific and comprehensive acoustic monitoring, with the express purpose of providing a robust body of data that would form a reference for evaluation of future effects of similar activities. In addition, the Navy has proactively secured funding and sought collaboration with NMFS and other experts to conduct future surveys of Washington inland waters that will provide much-needed updates to our understanding of marine mammal abundance and distribution in the region.

Comment 5: The Commission recommends that we complete an analysis of the impact of the proposed activities together with the cumulative impacts of all the other pertinent risk factors (including but not limited to the Navy's concurrent EHW–2 project) for marine mammals in the Hood Canal area.

Response: Section 101(a)(5)(D) of the MMPA requires NMFS to make a determination that the harassment incidental to a specified activity will have a negligible impact on the affected species or stocks of marine mammals, and will not result in an unmitigable adverse impact on the availability of marine mammals for taking for subsistence uses. Neither the MMPA nor NMFS' implementing regulations specify how to consider other activities

and their impacts on the same populations. However, consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into the negligible impact analysis via their impacts on the environmental baseline (e.g., as reflected in the density/distribution and status of the species, population size and growth rate, and ambient noise).

In addition, cumulative effects were addressed in the Navy's Environmental Assessment prepared for this action, as well as in the NEPA analyses and biological opinions prepared for other actions conducted at the NBKB waterfront. These documents, as well as the relevant Stock Assessment Reports, are part of NMFS' Administrative Record for this action, and provided the decision-maker with information regarding other activities in the action area that affect marine mammals, an analysis of cumulative impacts, and other information relevant to the determination made under the MMPA.

Comment 6: The Commission recommends that we encourage the Navy to combine future requests for IHAs for all activities that would occur in the same general area and within the same year rather than segmenting those activities and their associated impacts by requesting separate authorizations.

Response: We agree with the Commission's recommendation and have encouraged the Navy to do so. However, we do not have the statutory authority to require the Navy to combine such requests. With our encouragement, the Navy is working to develop a regionally comprehensive approach to environmental compliance for reasonably foreseeable small actions, such as pile replacement and repair projects. A major project such as the concurrent EHW–2 construction would likely remain as a standalone effort due to constraints related to planning, funding, and contracting.

Comment 7: The Commission recommends that we require the Navy to use the same data (e.g., source levels, sound attenuation factors, densities), methods, and justification for all pile driving and removal activities that occur during the same timeframe at NBKB.

Response: We concur with the Commission's recommendation and will require consistency from the Navy in future IHA requests. However, we are not overly concerned here because where there are inconsistencies they are due to use of conservative approaches. For example, in discussing source levels used for determining mitigation zones, the Commission notes that the Navy used a conservative estimate (i.e., the maximum source level) for the barge mooring project, but did not do so for the EHW–2 project. While the approach differs, conservatism is also built into the estimation of mitigation zones for EHW–2, not through use of a conservative source level, but by using the maximum radial distances to relevant thresholds, as measured during in site-specific acoustic monitoring. The modeled zones for the EHW–2 project were 22 and 5 m for the 180 and 190 dB zones, respectively, but the zones required of the Navy are 85 and 20 m, respectively. This more conservative approach was adopted at the urging and with the concurrence of the Commission in 2012. The Commission states that it is unclear why these inconsistencies are present, however, in each case the reason for the inconsistency and the rationale for our decision that use of an inconsistent approach is acceptable, if not desirable, is clearly presented in the associated FR notices.

Description of Marine Mammals in the Area of the Specified Activity

There are seven marine mammal species, four cetaceans and three pinnipeds, which may inhabit or transit through the waters nearby NBKB in the Hood Canal. These include the transient killer whale, harbor porpoise, Dall's porpoise (*Phocoenoides dalli dalli*), Steller sea lion (eastern stock only; *Eumetopias jubatus monteriensis*), California sea lion, harbor seal, and humpback whale (*Megaptera novaeangliae*). The Steller sea lion and humpback whale are the only marine mammals that may occur within the Hood Canal that are listed under the Endangered Species Act (ESA); the humpback whale is listed as endangered and the eastern distinct population segment (DPS) of Steller sea lion is listed as threatened. The Steller sea lion is typically present in low numbers in the Hood Canal only from approximately October through mid-April. The humpback whale is not typically present in Hood Canal, with no confirmed sightings found in the literature or the Orca Network database (*http://www.orcanetwork.org/*) prior to January and February 2012, when one individual was observed repeatedly over a period of several weeks. No sightings have been recorded since that time and we consider the humpback whale to be a rare visitor to Hood Canal at most. While the southern resident killer whale is resident to the inland waters of Washington and British Columbia, it has not been observed in the Hood Canal in over 15 years. Therefore, these three stocks were excluded from further analysis. The FR notice (78 FR 30273; May 22, 2013) summarizes the population status and abundance of these species, and the Navy's application provides detailed life history information.

Potential Effects of the Specified Activity on Marine Mammals

We have determined that pile driving, as outlined in the project description, has the potential to result in behavioral harassment of marine mammals that may be present in the project vicinity while construction activity is being conducted. Pile driving could potentially harass those pinnipeds that are in the water close to the project site, whether exposed to airborne or underwater sound. The FR notice (78 FR 30273; May 22, 2013) provides a detailed description of marine mammal hearing and of the potential effects of these construction activities on marine mammals.

Anticipated Effects on Habitat

The planned activities at NBKB will not result in permanent impacts to habitats used directly by marine mammals, such as haul-out sites, but may have potential short-term impacts to food sources such as forage fish and salmonids. There are no rookeries or major haul-out sites within 10 km (6.2 mi), foraging hotspots, or other ocean bottom structures of significant biological importance to marine mammals that may be present in the marine waters in the vicinity of the project area. Therefore, the main impact issue associated with the specified activity will be temporarily elevated sound levels and the associated direct effects on marine mammals, as discussed previously in this document. The most likely impact to marine mammal habitat occurs from pile driving effects on likely marine mammal prey (i.e., fish) near NBKB and minor impacts to the immediate substrate during construction activity associated with the barge mooring project. The FR notice (78 FR 30273; May 22, 2013) describes these potential impacts in greater detail.

Mitigation

In order to issue an incidental take authorization (ITA) under Section 101(a)(5)(D) of the MMPA, we must, where applicable, set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar

significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant).

Measurements from similar pile driving elsewhere at NBKB were coupled with practical spreading loss to estimate zones of influence (ZOIs; see ''Estimated Take by Incidental Harassment''); these values were used to develop mitigation measures for pile driving activities at NBKB. The ZOIs effectively represent the mitigation zones that will be established around each pile to prevent Level A harassment to marine mammals, while providing estimates of the areas within which Level B harassment might occur. In addition to the measures described later in this section, the Navy will employ the following standard mitigation measures:

(a) Conduct briefings between construction supervisors and crews, marine mammal monitoring team, acoustical monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

(b) Comply with applicable equipment sound standards and ensure that all construction equipment has sound control devices no less effective than those provided on the original equipment.

(c) For in-water heavy machinery work other than pile driving (using, e.g., standard barges, tug boats, barge-mounted excavators, or clamshell equipment used to place or remove material), if a marine mammal comes within 10 m, operations shall cease and vessels shall reduce speed to the minimum level required to maintain steerage and safe working conditions. This type of work could include the following activities: (1) Movement of the barge to the pile location; (2) positioning of the pile on the substrate via a crane (i.e., stabbing the pile); (3) removal of the pile from the water column/substrate via a crane (i.e., deadpull); or (4) the placement of sound attenuation devices around the piles. For these activities, monitoring will take place from 15 minutes prior to initiation until the action is complete.

Monitoring and Shutdown for Pile Driving

The following measures will apply to the Navy's mitigation through shutdown and disturbance zones:

Shutdown Zone—For all pile driving and removal activities, the Navy will establish a shutdown zone intended to contain the area in which SPLs equal or exceed the 180/190 dB rms acoustic injury criteria. The purpose of a shutdown zone is to define an area within which shutdown of activity will occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area), thus preventing injury, serious injury, or death of marine mammals. Radial distances for shutdown zones are shown in Table 1. However, a minimum shutdown zone of 10 m will be established during all pile driving and removal activities, regardless of the estimated zone. These precautionary measures are intended to prevent the already unlikely possibility of physical interaction with construction equipment and to further reduce any possibility of acoustic injury.

Disturbance Zone—Disturbance zones are the areas in which SPLs equal or exceed 160 and 120 dB rms (for pulsed and non-pulsed sound, respectively). Disturbance zones provide utility for monitoring conducted for mitigation purposes (i.e., shutdown zone monitoring) by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring of disturbance zones enables observers to be aware of and communicate the presence of marine mammals in the project area but outside the shutdown zone and thus prepare for potential shutdowns of activity. However, the primary purpose of disturbance zone monitoring is for documenting incidents of Level B harassment; disturbance zone monitoring is discussed in greater detail later (see ''Monitoring and Reporting''). Nominal radial distances for disturbance zones are shown in Tables 1 and 2. Given the size of the disturbance zone for vibratory pile driving, it is impossible to guarantee that all animals will be observed or to make comprehensive observations of fine-scale behavioral reactions to sound, and only a portion of the zone (e.g., what may be reasonably observed by visual observers stationed within the waterfront restricted area [WRA]) will be monitored.

In order to document observed incidences of harassment, monitors record all marine mammal observations, regardless of location. The observer's location, as well as the location of the pile being driven, is known from a GPS. The location of the animal is estimated as a distance from the observer, which is then compared to the location from the pile. If acoustic monitoring is being conducted for that pile, a received SPL may be estimated, or the received level may be estimated on the basis of past or subsequent acoustic monitoring. It may then be determined whether the animal was exposed to sound levels constituting incidental harassment in post-processing of observational and acoustic data, and a precise accounting of observed incidences of harassment created. Therefore, although the predicted distances to behavioral harassment thresholds are useful for estimating incidental harassment for purposes of authorizing levels of incidental take, actual take may be determined in part through the use of empirical data. That information may then be used to extrapolate observed takes to reach an approximate understanding of actual total takes.

Monitoring Protocols—Monitoring will be conducted before, during, and after pile driving activities. In addition, observers shall record all incidences of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven. Observations made outside the shutdown zone will not result in shutdown; that pile segment will be completed without cessation, unless the animal approaches or enters the shutdown zone, at which point all pile driving activities will be halted. Monitoring will take place from 15 minutes prior to initiation through 30 minutes post-completion of pile driving activities. Pile driving activities include the time to remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes. Please see the Marine Mammal Monitoring Plan (available at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm*), developed by the Navy in agreement with us, for full details of the monitoring protocols.

The following additional measures apply to visual monitoring:

(1) Monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Qualified observers are trained biologists, with the following minimum qualifications:

- Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;
- Advanced education in biological science, wildlife management, mammalogy, or related fields (bachelor's degree or higher is required);

• Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);
• Experience or training in the field identification of marine mammals, including the identification of behaviors;
• Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
• Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and
• Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

(2) Prior to the start of pile driving activity, the shutdown zone will be monitored for 15 minutes to ensure that it is clear of marine mammals. Pile driving will only commence once observers have declared the shutdown zone clear of marine mammals; animals will be allowed to remain in the shutdown zone (i.e., must leave of their own volition) and their behavior will be monitored and documented. The shutdown zone may only be declared clear, and pile driving started, when the entire shutdown zone is visible (i.e., when not obscured by dark, rain, fog, etc.). In addition, if such conditions should arise during impact pile driving that is already underway, the activity will be halted.

(3) If a marine mammal approaches or enters the shutdown zone during the course of pile driving operations, activity will be halted and delayed until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or 15 minutes have passed without re-detection of the animal. Monitoring will be conducted throughout the time required to drive a pile.

Sound Attenuation Devices

Bubble curtains shall be used during all impact pile driving. The device will distribute air bubbles around 100 percent of the piling perimeter for the full depth of the water column, and the lowest bubble ring shall be in contact with the mudline for the full circumference of the ring. Testing of the device by comparing attenuated and unattenuated strikes is not possible because of requirements in place to protect marbled murrelets (an ESA-listed bird species under the jurisdiction of the USFWS). However, in order to avoid loss of attenuation from design and implementation errors in the absence of such testing, a performance test of the device shall be conducted prior to initial use. The performance test shall confirm the calculated pressures and flow rates at each manifold ring. In addition, the contractor shall also train personnel in the proper balancing of air flow to the bubblers and shall submit an inspection/performance report to the Navy within 72 hours following the performance test.

Timing Restrictions

In Hood Canal, designated timing restrictions exist for pile driving activities to avoid in-water work when salmonids and other spawning forage fish are likely to be present. The in-water work window is July 16–February 15. The barge mooring project will occur during a portion of that period, from July 16–September 30. During the majority of this timeframe, impact pile driving will only occur starting two hours after sunrise and ending two hours before sunset due to marbled murrelet nesting season. After September 23, in-water construction activities will occur during daylight hours (sunrise to sunset).

Soft Start

The use of a soft-start procedure is believed to provide additional protection to marine mammals by warning or providing a chance to leave the area prior to the hammer operating at full capacity, and typically involves a requirement to initiate sound from vibratory hammers for fifteen seconds at reduced energy followed by a 30-second waiting period. This procedure is repeated two additional times. However, implementation of soft start for vibratory pile driving during previous pile driving work at NBKB has led to equipment failure and serious human safety concerns; those issues were detailed in the FR notice (78 FR 30273; May 22, 2013). Therefore, vibratory soft start is not required as a mitigation measure for this project, as we have determined it to not currently be practicable due to safety concerns. We have further determined this measure unnecessary to providing the means of effecting the least practicable impact on marine mammals and their habitat. For impact driving, soft start will be required, and contractors will provide an initial set of strikes from the impact hammer at reduced energy, followed by a 30-second waiting period, then two subsequent reduced energy strike sets. The reduced energy of an individual hammer cannot be quantified because of variation in individual drivers. The actual number of strikes at reduced energy will vary because operating the hammer at less than full power results in ''bouncing'' of the hammer as it strikes the pile, resulting in multiple ''strikes''. Soft start for impact driving will be required at the beginning of each day's pile driving work and at any time following a cessation of impact pile driving of 30 minutes or longer.

We have carefully evaluated the applicant's mitigation measures and considered a range of other measures in the context of ensuring that we prescribe the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another: (1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals; (2) the proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and (3) the practicability of the measure for applicant implementation, including consideration of personnel safety, and practicality of implementation.

Based on our evaluation of the applicant's planned measures, as well as any other potential measures that may be relevant to the specified activity, we have determined that these mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that we must, where applicable, set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Please see the Navy's Marine Mammal Monitoring Plan for

full details of the requirements for monitoring and reporting.

Visual Marine Mammal Observations

The Navy will collect sighting data and behavioral responses to construction for marine mammal species observed in the region of activity during the period of activity. All observers will be trained in marine mammal identification and behaviors and are required to have no other construction-related tasks while conducting monitoring. The Navy will monitor the shutdown zone and disturbance zone before, during, and after pile driving, with observers located at the best practicable vantage points. Based on our requirements, the Navy will implement the following procedures for pile driving:

- MMOs will be located at the best vantage point(s) in order to properly see the entire shutdown zone and as much of the disturbance zone as possible.
- During all observation periods, observers will use binoculars and the naked eye to search continuously for marine mammals.
- If the shutdown zones are obscured by fog or poor lighting conditions, pile driving at that location will not be initiated until that zone is visible. Should such conditions arise while impact driving is underway, the activity will be halted.
- The shutdown and disturbance zones around the pile will be monitored for the presence of marine mammals before, during, and after any pile driving or removal activity.

Individuals implementing the monitoring protocol will assess its effectiveness using an adaptive approach. Monitoring biologists will use their best professional judgment throughout implementation and seek improvements to these methods when deemed appropriate. Any modifications to protocol will be coordinated between NMFS and the Navy.

Data Collection

We require that observers use approved data forms. Among other pieces of information, the Navy will record detailed information about any implementation of shutdowns, including the distance of animals to the pile and description of specific actions that ensued and resulting behavior of the animal, if any. In addition, the Navy will attempt to distinguish between the number of individual animals taken and the number of incidences of take. We require that, at a minimum, the following information be collected on the sighting forms:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Weather parameters (e.g., percent cover, visibility);
- Water conditions (e.g., sea state, tide state);
- Species, numbers, and, if possible, sex and age class of marine mammals;
- Description of any observable marine mammal behavior patterns, including bearing and direction of travel, and if possible, the correlation to SPLs;
- Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- Locations of all marine mammal observations; and
- Other human activity in the area.

Reporting

A draft report will be submitted to NMFS within 90 working days of the completion of marine mammal monitoring. The report will include marine mammal observations pre-activity, during-activity, and post-activity during pile driving days, and will also provide descriptions of any adverse responses to construction activities by marine mammals and a complete description of all mitigation shutdowns and the results of those actions and a refined take estimate based on the number of marine mammals observed during the course of construction. A final report will be prepared and submitted within 30 days following resolution of comments on the draft report.

Estimated Take by Incidental Harassment

With respect to the activities described here, the MMPA defines ''harassment'' as: ''Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].''

All anticipated takes will be by Level B harassment, involving temporary changes in behavior. The planned mitigation and monitoring measures are expected to minimize the possibility of injurious or lethal takes such that take by Level A harassment, serious injury or mortality is considered discountable. However, it is unlikely that injurious or lethal takes would occur even in the absence of the planned mitigation and monitoring measures.

If a marine mammal responds to a stimulus by changing its behavior (e.g., through relatively minor changes in locomotion direction/speed or vocalization behavior), the response may or may not constitute taking at the individual level, and is unlikely to affect the stock or the species as a whole. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on animals or on the stock or species could potentially be significant (Lusseau and Bejder, 2007; Weilgart, 2007). Given the many uncertainties in predicting the quantity and types of impacts of sound on marine mammals, it is common practice to estimate how many animals are likely to be present within a particular distance of a given activity, or exposed to a particular level of sound. This practice potentially overestimates the numbers of marine mammals taken. For example, during the past ten years, killer whales have been observed within the project area twice. On the basis of that information, an estimated amount of potential takes for killer whales is presented here. However, while a pod of killer whales could potentially visit again during the project timeframe, and thus be taken, it is more likely that they will not. Although incidental take of killer whales and Dall's porpoises was authorized for 2011–12 activities at NBKB on the basis of past observations of these species, no such takes were recorded and no individuals of these species were observed. Similarly, estimated actual take levels (observed takes extrapolated to the remainder of unobserved but ensonified area) were significantly less than authorized levels of take for the remaining species.

The project area is not believed to be particularly important habitat for marine mammals, nor is it considered an area frequented by marine mammals, although harbor seals are year-round residents of Hood Canal and sea lions are known to haul-out on submarines and other man-made objects at the NBKB waterfront (although typically at a distance of a mile or greater from the project site). Therefore, behavioral disturbances that could result from anthropogenic sound associated with these activities are expected to affect only a relatively small number of individual marine mammals, although those effects could be recurring over the life of the project if the same individuals remain in the project vicinity.

The Navy has requested authorization for the incidental taking of small numbers of California sea lions, harbor

seals, transient killer whales, and harbor porpoises in the Hood Canal that may result from pile driving during construction activities associated with the barge mooring project described previously in this document.

The humpback whale is not expected to occur in the project area, and Steller sea lions are not expected to occur during the project timeframe. The earliest documented occurrence of Steller sea lions at NBKB occurred on September 30, 2010, when five individuals were observed at Delta Pier during daily surveys. During monitoring associated with the 2011 TPP, Steller sea lions were documented as arriving on October 8, but had not previously been regularly observed prior to November.

Marine Mammal Densities

For all species, the best scientific information available was used to derive density estimates and the maximum appropriate density value for each species for each site was used in the marine mammal take assessment calculation. These values were derived or confirmed by experts convened to develop such information for use in Navy environmental compliance efforts in the Pacific Northwest (Navy, 2013). For harbor seals, this involved published literature describing harbor seal research conducted in Washington and Oregon as well as more specific counts conducted in Hood Canal (Huber *et al.,* 2001; Jeffries *et al.,* 2003). The best information available for the remaining species in Hood Canal came from surveys conducted by the Navy at the NBKB waterfront or in the vicinity of the project area.

Beginning in April 2008, Navy personnel have recorded sightings of marine mammals occurring at known haul-outs along the NBKB waterfront, including docked submarines or other structures associated with NBKB docks and piers and the nearshore pontoons of the floating security fence. Sightings of marine mammals within the waters adjoining these locations were also recorded. Sightings were attempted whenever possible during a typical work week (i.e., Monday through Friday), but inclement weather, holidays, or security constraints often precluded surveys. These sightings took place frequently, although without a formal survey protocol. During the surveys, staff visited each of the above-mentioned locations and recorded observations of marine mammals. Surveys were conducted using binoculars and the naked eye from shoreline locations or the piers/wharves themselves. Because these surveys consist of opportunistic sighting data from shore-based observers, largely of hauled-out animals, there is no associated survey area appropriate for use in calculating a density from the abundance data. Data were compiled for the period from April 2008 through December 2012 for analysis in this IHA, and these data provide the basis for take estimation for California sea lions. Please note that, although we erroneously stated in the FR notice that data were compiled only through November 2011, the data actually displayed in Table 6 of that document was indeed compiled through December 2012. Other information, including sightings data from other Navy survey efforts at NBKB, is available for this species, but these data provide the most conservative (i.e., highest) local abundance estimates (and thus the highest estimates of potential take).

In addition, vessel-based marine wildlife surveys were conducted according to established survey protocols during July through September 2008 and November through May 2009–10 (Tannenbaum *et al.,* 2009, 2011). Eighteen complete surveys of the nearshore area resulted in observations of four marine mammal species (harbor seal, California sea lion, harbor porpoise, and Dall's porpoise). These surveys operated along pre-determined transects parallel to the shoreline from the nearshore out to approximately 1,800 ft (549 m) from shoreline, at a spacing of 100 yd, and covered the entire NBKB waterfront (approximately 3.9 km^2 per survey) at a speed of 5 kn or less. Two observers recorded sightings of marine mammals both in the water and hauled out, including date, time, species, number of individuals, age (juvenile, adult), behavior (swimming, diving, hauled out, avoidance dive), and haul-out location. Positions of marine mammals were obtained by recording distance and bearing to the animal with a rangefinder and compass, noting the concurrent location of the boat with GPS, and, subsequently, analyzing these data to produce coordinates of the locations of all animals detected. These surveys resulted in the only observation of a Dall's porpoise near NBKB.

The Navy also conducted vessel-based line transect surveys in Hood Canal on non-construction days during the 2011 TPP in order to collect additional data for species present in Hood Canal. These surveys detected three marine mammal species (harbor seal, California sea lion, and harbor porpoise), and included surveys conducted in both the main body of Hood Canal, near the project area, and baseline surveys conducted for comparison in Dabob Bay, an area of Hood Canal that is not affected by sound from Navy actions at the NBKB waterfront. The surveys operated along pre-determined transects that followed a double saw-tooth pattern to achieve uniform coverage of the entire NBKB waterfront. The vessel traveled at a speed of approximately 5 kn when transiting along the transect lines. Two observers recorded sightings of marine mammals both in the water and hauled out, including the date, time, species, number of individuals, and behavior (swimming, diving, etc.). Positions of marine mammals were obtained by recording the distance and bearing to the animal(s), noting the concurrent location of the boat with GPS, and subsequently analyzing these data to produce coordinates of the locations of all animals detected. Sighting information for harbor porpoises was corrected for detectability ($g(0) = 0.54$; Barlow, 1988; Calambokidis *et al.,* 1993; Carretta *et al.,* 2001). Distance sampling methodologies were used to estimate densities of animals for the data. This information provides the best information for harbor porpoises.

The cetaceans, as well as the harbor seal, appear to range throughout Hood Canal; therefore, the analysis in this proposed IHA assumes that harbor seal, transient killer whale, harbor porpoise, and Dall's porpoise are uniformly distributed in the project area. However, it should be noted that there have been no observations of cetaceans within the floating security barriers at NBKB; these barriers thus appear to effectively prevent cetaceans from approaching the shutdown zones. Although the Navy will implement a precautionary shutdown zone for cetaceans, anecdotal evidence suggests that cetaceans are not at risk of Level A harassment at NBKB even from louder activities (e.g., impact pile driving). The California sea lion does not appear to utilize most of Hood Canal. The sea lions appear to be attracted to the man-made haul-out opportunities along the NBKB waterfront while dispersing for foraging opportunities elsewhere in Hood Canal. California sea lions were not reported during aerial surveys of Hood Canal (Jeffries *et al.,* 2000).

Description of Take Calculation

The take calculations presented here rely on the best data currently available for marine mammal populations in the Hood Canal. The formula was developed for calculating take due to pile driving activity and applied to each group-specific sound impact threshold. The formula is founded on the following assumptions:

- Mitigation measures (e.g., bubble curtain) will be utilized, as discussed previously;
- All marine mammal individuals potentially available are assumed to be present within the relevant area, and thus incidentally taken;
- An individual can only be taken once during a 24-h period; and,
- There were will be twenty total days of activity.
- Exposures to sound levels above the relevant thresholds equate to take, as defined by the MMPA.

The calculation for marine mammal takes is estimated by:

Exposure estimate = (n * ZOI) * days of total activity

Where:

n = density estimate used for each species/season

ZOI = sound threshold ZOI impact area; the area encompassed by all locations where the SPLs equal or exceed the threshold being evaluated

n * ZOI produces an estimate of the abundance of animals that could be present in the area for exposure, and is rounded to the nearest whole number before multiplying by days of total activity.

The ZOI impact area is the estimated range of impact to the sound criteria. The distances specified in Table 1 were used to calculate ZOIs around each pile. All impact pile driving take calculations were based on the estimated threshold ranges assuming attenuation of 8 dB from use of a bubble curtain. The ZOI impact area took into consideration the possible affected area of the Hood Canal from the pile driving site furthest from shore with attenuation due to land shadowing from bends in the canal. Because of the close proximity of some of the piles to the shore, the narrowness of the canal at the project area, and the maximum fetch, the ZOIs for each threshold are not necessarily spherical and may be truncated.

While pile driving can occur any day throughout the in-water work window, and the analysis is conducted on a per day basis, only a fraction of that time (typically a matter of hours on any given day) is actually spent pile driving. Acoustic monitoring conducted as part of the TPP demonstrated that Level B harassment zones for vibratory pile driving are likely to be significantly smaller than the zones estimated through modeling based on measured source levels and practical spreading loss. Also of note is the fact that the effectiveness of mitigation measures in reducing takes is typically not quantified in the take estimation process. Here, we do explicitly account for an assumed level of efficacy for use of the bubble curtain, but not for the soft start associated with impact driving. In addition, equating exposure with response (i.e., a behavioral response meeting the definition of take under the MMPA) is simplistic and conservative assumption. For these reasons, these take estimates are likely to be conservative.

Airborne Sound—No incidents of incidental take resulting solely from airborne sound are likely, as distances to the harassment thresholds will not reach areas where pinnipeds may haul out. Harbor seals can haul out at a variety of natural or manmade locations, but the closest known harbor seal haul-out is at the Dosewallips River mouth (London, 2006) and Navy waterfront surveys and boat surveys have found it rare for harbor seals to haul out along the NBKB waterfront (Agness and Tannenbaum, 2009; Tannenbaum *et al.,* 2009, 2011; Navy, 2010). Individual seals have occasionally been observed hauled out on pontoons of the floating security fence within the restricted areas of NBKB, but this area is not with the airborne disturbance ZOI. The Service Pier is elevated at least twenty feet above the surface of the water and is inaccessible to pinnipeds, and seals have not been observed hauled out on the floating Port Operations pier sections or on the shoreline adjacent to the Service Pier. Sea lions typically haul out on submarines docked at Delta Pier, approximately one mile from the project site.

We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with heads above water. However, these animals will previously have been 'taken' as a result of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Multiple incidents of exposure to sound above NMFS' thresholds for behavioral harassment are not believed to result in increased behavioral disturbance, in either nature or intensity of disturbance reaction. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted.

California Sea Lion—California sea lions occur regularly in the vicinity of the project site from August through mid-June, as determined by Navy waterfront surveys conducted from April 2008 through December 2012 (Table 3). With regard to the range of this species in Hood Canal and the project area, it is assumed on the basis of waterfront observations (Agness and Tannenbaum, 2009; Tannenbaum *et al.,* 2009, 2011) that the opportunity to haul out on submarines docked at Delta Pier is a primary attractant for California sea lions in Hood Canal, as they are not typically observed elsewhere in Hood Canal. Their haul-out sites are not within the largest underwater ZOI, because sound will encounter land before reaching the haul-out site (see Figure 6–2 in the Navy's application). Abundance is calculated as the monthly average of the maximum number observed in a given month, as opposed to the overall average (Table 3). That is, the maximum number of animals observed on any one day in a given month was averaged for 2008–12, providing a monthly average of the maximum daily number observed. The largest monthly average (58 animals) was recorded in November, as was the largest single daily count (81 in 2011). The first California sea lion was observed at NBKB in August 2009, and their occurrence has been increasing since that time (Navy, 2012).

California sea lion density for Hood Canal was calculated to be 0.28 animals/km^2 for purposes of the Navy Marine Species Density Database (Navy, 2013). However, this density was derived by averaging data collected year-round. This project will occur during the months when California sea lions are the least abundant in Hood Canal, so it is more appropriate to use data collected at the NBKB waterfront during those months (August-September; we exclude July because it is likely that the majority of work will occur in August and September). In addition, local observations show that sea lions are attracted to haul-out opportunities at NBKB, resulting in greater local abundance than is indicated by the NMSDD density value. In our analysis contained in the FR notice (78 FR 30273; May 22, 2013), and based on the Navy's request for take authorization, we considered the highest number of individual California sea lions observed hauled out at NBKB during the July-September timeframe (i.e., 33), which occurred at the end of September 2010. Exposures were calculated assuming 33 individuals could be present, and therefore exposed to sound exceeding the behavioral harassment threshold, on each day of pile driving. We noted in that document that this was an extremely conservative methodology, but chose to carry it forward. However, in subsequent discussions with the Marine Mammal Commission, we determined that this conservative

methodology was likely unwarranted and resulted in unrealistic take estimates (i.e., a much greater take estimate for California sea lions than for harbor seals), given the observed primacy of harbor seals in waterfront observations for other actions at NBKB. Therefore, we have determined that it is more appropriate to use the monthly average from August-September, which considers the much lower observed abundances from August and early September (when the majority of project activity is likely to be completed). We still conservatively assume that all individuals potentially present (i.e., seven individuals; see Table 3) will be taken on any given day of activity.

TABLE 3—CALIFORNIA SEA LION SIGHTING INFORMATION FROM NBKB, APRIL 2008–DECEMBER 2012

Month	Number of surveys	Number of surveys with animals present	Frequency of presence [1]	Abundance [2]
January	47	36	0.77	31.0
February	50	43	0.86	38.0
March	47	45	0.96	53.3
April	67	55	0.82	45.4
May	72	58	0.81	29.4
June	73	17	0.23	7.4
July	61	1	0.02	0.6
August	65	12	0.18	2.6
September	54	31	0.57	20.4
October	65	61	0.94	51.8
November	56	56	1	60.2
December	54	44	0.81	49.6
Total or average (Aug–Sep only)	119	43	0.36	10.7

Totals (number of surveys) and averages (frequency and abundance) presented for project period (August–September) only. Information from other months presented for reference. Average abundance is weighted by monthly survey effort.

[1] Frequency is the number of surveys with California sea lions present/number of surveys conducted.

[2] Abundance is calculated as the monthly average of the maximum daily number observed in a given month.

Harbor Seal—Jeffries *et al.* (2003) conducted aerial surveys of the harbor seal population in Hood Canal in 1999 for the Washington Department of Fish and Wildlife and reported 711 harbor seals hauled out. The authors adjusted this abundance with a correction factor of 1.53 to account for seals in the water, which were not counted, and estimated that there were 1,088 harbor seals in Hood Canal. The correction factor (1.53) was based on the proportion of time seals spend on land versus in the water over the course of a day, and was derived by dividing one by the percentage of time harbor seals spent on land. These data came from tags (VHF transmitters) applied to harbor seals at six areas (Grays Harbor, Tillamook Bay, Umpqua River, Gertrude Island, Protection/Smith Islands, and Boundary Bay, BC) within two different harbor seal stocks (the coastal stock and the inland waters of WA stock) over four survey years. The Hood Canal population is part of the inland waters stock, and while not specifically sampled, Jeffries *et al.* (2003) found the VHF data to be broadly applicable to the entire stock. The tagging research in 1991 and 1992 conducted by Huber *et al.* (2001) and Jeffries *et al.* (2003) used the same methods for the 1999 and 2000 survey years. These surveys indicated that approximately 35 percent of harbor seals are in the water versus hauled out on a daily basis (Huber *et al.,* 2001; Jeffries *et al.,* 2003). Exposures were calculated using a density derived from the number of harbor seals that are present in the water at any one time (35 percent of 1,088, or approximately 381 individuals), divided by the area of the Hood Canal (358.44 km^2) and the formula presented previously. The aforementioned area of Hood Canal represents a change from that cited previously for authorizations associated with Navy activities in Hood Canal, and represents a correction to our understanding of the methodology used in *Jeffries et al.* (2003).

We recognize that over the course of the day, while the proportion of animals in the water may not vary significantly, different individuals may enter and exit the water. However, fine-scale data on harbor seal movements within the project area on time durations of less than a day are not available. Previous monitoring experience from Navy actions conducted from in the same project area has indicated that this density provides an appropriate estimate of potential exposures. However, the density of harbor seals calculated in this manner (1.06 animals/km^2) is corroborated by results of the Navy's vessel-based marine mammal surveys at NBKB in 2008 and 2009–10, in which an average of five individual harbor seals per survey was observed in the 3.9 km^2 survey area (density = 1.3 animals/km^2) (Tannenbaum *et al.,* 2009, 2011).

Killer Whales—Transient killer whales are uncommon visitors to Hood Canal, and may be present anytime during the year. Transient pods (six to eleven individuals per event) were observed in Hood Canal for lengthy periods of time (59–172 days) in 2003 (January-March) and 2005 (February-June), feeding on harbor seals (London, 2006). These whales used the entire expanse of Hood Canal for feeding. West Coast transient killer whales most often travel in small pods (Baird and Dill 1996). Houghton reported to the Navy, from unpublished data, that the most commonly observed group size in Puget Sound (defined as from Admiralty Inlet south and up through Skagit Bay) from 2004–2010 data is six whales.

The density value derived for the Navy Marine Species Density Database is 0.0019 animals/km^2 (Navy, 2013), which would result in a prediction that zero animals will be harassed by the project activities. However, while transient killer whales are rare in the Hood Canal, it is possible that a pod of animals could be present. In the event that this occurred, the animals would not assume a uniform distribution as is implied by the density estimate. Therefore, we conservatively assume that a single pod of whales (defined as six whales) could be present in the

vicinity of the project for the entire duration.

Dall's Porpoise

Dall's porpoises may be present in the Hood Canal year-round and could occur as far south as the project site. Their use of inland Washington waters, however, is mostly limited to the Strait of Juan de Fuca. One individual has been observed by Navy staff in deeper waters of Hood Canal (Tannenbaum *et al.,* 2009, 2011). The Navy Marine Species Density Database assumes a negligible value of 0.001 animals/1,000 km^2 for Dall's porpoises in the Hood Canal, which represents species that have historically been observed in an area but have no regular presence. Use of this density value results in a prediction that zero animals will be exposed to sound above the behavioral harassment threshold, and the Navy has not requested any take authorization for Dall's porpoises.

Harbor Porpoise

During vessel-based line transect surveys on non-construction days during the TPP, harbor porpoises were frequently sighted within several kilometers of the base, mostly to the north or south of the project area, but occasionally directly across from the Bangor waterfront on the far side of Toandos Peninsula. Harbor porpoise presence in the immediate vicinity of the base (i.e., within 1 km) remained low. These data were used to generate a density for Hood Canal. Based on guidance from other line transect surveys conducted for harbor porpoises using similar monitoring parameters (e.g., boat speed, number of observers) (Barlow, 1988; Calambokidis *et al.,* 1993; Caretta *et al.,* 2001), the Navy determined the effective strip width for the surveys to be one kilometer, or a perpendicular distance of 500 m from the transect to the left or right of the vessel. The effective strip width was set at the distance at which the detection probability for harbor porpoises was equivalent to one, which assumes that all individuals on a transect are detected. Only sightings occurring within the effective strip width were used in the density calculation. By multiplying the trackline length of the surveys by the effective strip width, the total area surveyed during the surveys was 471.2 km^2. Thirty-eight individual harbor porpoises were sighted within this area, resulting in a density of 0.0806 animals per km^2. To account for availability bias, or the animals which are unavailable to be detected because they are submerged, the Navy utilized a g(0) value of 0.54, derived from other similar line transect surveys (Barlow, 1988; Calambokidis *et al.,* 1993; Carretta *et al.,* 2001). This resulted in a corrected density of 0.149 harbor porpoises per km^2. For comparison, 274.27 km^2 of trackline survey effort in nearby Dabob Bay produced a corrected density estimate of 0.203 harbor porpoises per km^2.

TABLE 4—NUMBER OF POTENTIAL INCIDENTAL TAKES OF MARINE MAMMALS WITHIN VARIOUS ACOUSTIC THRESHOLD ZONES

Species	Density	Underwater		Total authorized takes
		Impact injury threshold [1]	Vibratory disturbance threshold (120 dB) [2]	
California sea lion	[4] 0.28	0	220	220
Harbor seal	1.06	0	340	340
Killer whale	[5] 0.0019	0	120	120
Dall's porpoise	0.000001	0	0	0
Harbor porpoise	0.149	0	40	40

[1] Acoustic injury threshold for impact pile driving is 190 dB for pinnipeds and 180 dB for cetaceans.
[2] Impact pile driving will always occur on the same day as vibratory pile driving, and the 160-dB acoustic harassment zone associated with impact pile driving is considered subsumed by the 120-dB harassment zone produced by vibratory driving. Therefore, takes are not calculated separately for the two zones.
[4] A maximum abundance estimate of 11 animals present per day during the project timeframe was used for take estimation.
[5] Here we assume that a single pod of transient killer whales (defined as six whales) may be present for the duration of the work period (twenty days).

Negligible Impact and Small Numbers Analysis and Determinations

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' In making a negligible impact determination, NMFS considers a variety of factors, including but not limited to: (1) The number of anticipated mortalities; (2) the number and nature of anticipated injuries; (3) the number, nature, intensity, and duration of Level B harassment; and (4) the context in which the take occurs.

Small Numbers Analysis

The proposed numbers of animals authorized to be taken for California sea lions, harbor seals, and harbor porpoise would be considered small relative to the relevant stocks or populations (less than one percent for California sea lions and harbor porpoise and less than three percent for harbor seals) even if each estimated taking occurred to a new individual—an extremely unlikely scenario, as, for pinnipeds occurring at the NBKB waterfront, there will almost certainly be some overlap in individuals present day-to-day. Further, for the pinniped species, these takes could potentially occur only within some small portion of the overall regional stock. Of the estimated 296,500 California sea lions, only certain adult and subadult males—believed to number approximately 3,000–5,000 by Jeffries *et al.* (2000)—travel north during the non-breeding season. That number has almost certainly increased with the population of California sea lions—the 2000 Stock Assessment Report for California sea lions reported an estimated population size of 204,000–214,000 animals—but likely remains a relatively small portion of the overall population. For harbor seals, animals found in Hood Canal belong to a closed, resident population estimated at approximately 1,000 animals by Jeffries *et al.* (2003), and takes are likely to occur only within some portion of that closed population, rather than to animals from the Washington inland

waters stock as a whole. For transient killer whales, we estimate take based on an assumption that a single pod of whales, comprising six individuals, is present in the vicinity of the project area for the entire duration of the project. These six individuals represent a small number of transient killer whales, for which a conservative minimum estimate of 354 animals was given in the 2011 Stock Assessment Reports. With the exception of the bubble curtain, potential efficacy of mitigation measures in terms of reduction in numbers and/or intensity of incidences of take has not been quantified. Therefore, these take numbers are likely to be conservative.

Negligible Impact Analysis

Pile driving activities associated with the barge mooring project, as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the proposed activities may result in take, in the form of Level B harassment (behavioral disturbance) only, from airborne or underwater sounds generated from pile driving. Potential takes could occur if individuals of these species are present in the ensonified zone when pile driving is happening, which is likely to occur because (1) Harbor seals, which are frequently observed along the NBKB waterfront, are present within the WRA; (2) sea lions, which are less frequently observed, transit the WRA en route to haul-outs to the north at Delta Pier; or (3) cetaceans or pinnipeds transit the larger Level B harassment zone outside of the WRA.

No injury, serious injury, or mortality is anticipated given the methods of installation and measures designed to minimize the possibility of injury to marine mammals. The potential for these outcomes is minimized through the construction method and the implementation of the planned mitigation measures. Specifically, vibratory hammers will be the primary method of installation, and this activity does not have significant potential to cause injury to marine mammals due to the relatively low source levels produced (less than 190 dB) and the lack of potentially injurious source characteristics. Impact pile driving produces short, sharp pulses with higher peak levels and much sharper rise time to reach those peaks. When impact driving is necessary, required measures (use of a sound attenuation system, which reduces overall source levels as well as dampening the sharp, potentially injurious peaks, and implementation of shutdown zones) significantly reduce any possibility of injury. Likewise, Level B harassment will be reduced to the level of least practicable adverse impact through the use of mitigation measures described herein. that, given sufficient ''notice'' through mitigation measures including soft start (for impact driving), marine mammals are expected to move away from a sound source that is annoying prior to its becoming potentially injurious, and the likelihood that marine mammal detection ability by trained observers is high under the environmental conditions described for Hood Canal, enabling the implementation of shutdowns to avoid injury, serious injury, or mortality.

Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from past projects at NBKB, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. In response to vibratory driving, harbor seals (which may be somewhat habituated to human activity along the NBKB waterfront) have been observed to orient towards and sometimes move towards the sound.

For pinnipeds, no rookeries are present in the project area, there are no haul-outs other than those provided opportunistically by man-made objects, and the project area is not known to provide foraging habitat of any special importance. No cetaceans are expected within the WRA. The pile driving activities analyzed here are similar to other nearby construction activities within the Hood Canal, including two recent projects conducted by the Navy at the same location (test pile project and EHW–1 pile replacement project) as well as work conducted in 2005 for the Hood Canal Bridge (SR–104) by the Washington Department of Transportation, which have taken place with no reported injuries or mortality to marine mammals, and no known long-term adverse consequences from behavioral harassment.

In summary, this negligible impact analysis is founded on the following factors: (1) The possibility of injury, serious injury, or mortality may reasonably be considered discountable; (2) the anticipated incidences of Level B harassment consist of, at worst, temporary modifications in behavior; (3) the absence of any major rookeries and only a few isolated and opportunistic haul-out areas near or adjacent to the project site; (4) the absence of cetaceans within the WRA and generally sporadic occurrence outside the WRA; (5) the absence of any other known areas or features of special significance for foraging or reproduction within the project area; (6) the presumed efficacy of the planned mitigation measures in reducing the effects of the specified activity to the level of least practicable impact. In addition, none of these stocks are listed under the ESA or considered of special status (e.g., depleted or strategic) under the MMPA, and all four are thought to be increasing. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, including those conducted at the same time of year and in the same location, demonstrate that the potential effects of the specified activity will have only short-term effects on individuals. The specified activity is not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.

Determinations

While the number of marine mammals potentially incidentally harassed will depend on the distribution and abundance of marine mammals in the vicinity of the survey activity, we find that the number of potential takings, by level B harassment only, is small relative to the relevant regional stock or population numbers, and that the effect of the activity will be mitigated to the level of least practicable impact through implementation of the mitigation and monitoring measures described previously. Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, we find that the total taking from the activity will have a negligible impact on the affected species or stocks.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

No tribal subsistence hunts are held in the vicinity of the project area; thus, temporary behavioral impacts to individual animals will not affect any subsistence activity. Further, no population or stock level impacts to marine mammals are anticipated or authorized. As a result, no impacts to the availability of the species or stock to the Pacific Northwest treaty tribes are expected as a result of the activities. Therefore, no relevant subsistence uses of marine mammals are implicated by this action.

Endangered Species Act (ESA)

There are no ESA-listed marine mammals expected to occur in the action area during the proposed action timeframe; therefore, no consultation under the ESA is required for such species.

National Environmental Policy Act (NEPA)

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), as implemented by the regulations published by the Council on Environmental Quality (40 CFR parts 1500–1508), the Navy prepared an Environmental Assessment (EA) to consider the direct, indirect and cumulative effects to the human environment resulting from the barge mooring project. NMFS made the Navy's EA available to the public for review and comment, in relation to its suitability for adoption by NMFS in order to assess the impacts to the human environment of issuance of an IHA to the Navy. Also in compliance with NEPA and the CEQ regulations, as well as NOAA Administrative Order 216–6, NMFS has reviewed the Navy's EA, determined it to be sufficient, and adopted that EA and signed a Finding of No Significant Impact (FONSI) on July 3, 2013. The Navy's EA and NMFS' FONSI for this action may be found at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.*

Authorization

As a result of these determinations, we have issued an IHA to the Navy to conduct the described activities in the Hood Canal from the period of July 16, 2013, through September 30, 2013, provided the previously described mitigation, monitoring, and reporting requirements are incorporated.

Dated: July 10, 2013.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–17405 Filed 7–18–13; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add services to the Procurement List that will be provided by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and services previously furnished by such agencies.

DATES: *Comments Must Be Received On Or Before:* 8/19/2013.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 10800, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following services are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Services

Service Type/Location: Custodial Service, Superior National Forest Supervisors Office, 8901 Grand Avenue, Duluth, MN
NPA: Goodwill Industries Vocational Enterprises, Inc., Duluth, MN
Contracting Activity: Department of Agriculture, Forest Service, Superior National Forest, Duluth, MN
Service Type/Location: Vehicle Marshaling Service, GSA Rocky Mountain Region, Rapid City, SD
NPA: BH Services, Inc., Elsworth AFB, SD
Contracting Activity: GSA/FSS Regional Fleet MGT Office, Fort Worth, TX
Service Type/Location: Secure Document Destruction Service, Blanchfield Army Community Hospital, 2424 20th Street, Fort Campbell, KY
NPA: Goodwill Industries of Kentucky, Inc., Louisville, KY
Contracting Activity: DEPT OF THE ARMY, W40M SOUTHEAST RGNL CONTRG OFC, FORT GORDON, GA
Service Type/Location: Janitorial Service, US Immigration and Customs Enforcement, VA Hudson Valley HealthCare System Campus, Building 7 (Floors 1, 2, 3 & Basement), Route 9D, Castle Point, NY
NPA: Occupations, Inc., Middletown, NY
Contracting Activity: DEPARTMENT OF HOMELAND SECURITY, U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT, WASHINGTON, DC

Deletions

The following products and services are proposed for deletion from the Procurement List:

Products

NSN: 8465–01–592–1361—Sheath, Combination Tool Plastic
NPA: Development Workshop, Inc., Idaho Falls, ID
Contracting Activity: General Services Administration, Fort Worth, TX
NSN: 8125–00–NIB–0031—Spray Bottle, GS High Dilution 256 Neutral Disinfectant, Silk Screened, 12–32oz bottles
NPA: Susquehanna Association for the Blind and Vision Impaired, Lancaster, PA
Contracting Activity: Department Of Veterans Affairs, NAC, Hines, IL

Services

Service Type/Location: Industrial Laundry Service, Bureau of Engraving and Printing, 9000 Blue Mound Road, Fort Worth, TX
NPA: Goodwill Industrial Services of Fort Worth, Inc., Fort Worth, TX
Contracting Activity: Dept of Treasury, Bureau Of Engraving And Printing, Washington DC
Service Types/Location: Mailroom/Communications Center Operation, Administrative Service, Department of Agriculture, Farm Service Agency, 6501 Beacon Drive, Kansas City, MO
NPA: JobOne, Independence, MO
Contracting Activity: Dept of Agriculture, Farm Service Agency, Kansas City Acquisition Branch, Kansas City, MO

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2013–17372 Filed 7–18–13; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2013–OS–0161]

Proposed Collection; Comment Request

AGENCY: Defense Finance and Accounting Service (DFAS), DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the DFAS announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 17, 2013.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information. Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Finance and Accounting Services-Cleveland, 1240 East 9th Street, NP 7th Floor, Cleveland, OH 44199, ATTN: Ms. Laurie Eldridge, *laurie.eldridge@dfas.mil,* 216–204–3631.

Title; Associated Form; and OMB Number: DD Form 397, Claim Certification and Voucher for Death Gratuity Payment, OMB 0730–0017.

Needs and Uses: The information collection requirement allows the government to collect the signatures and information needed to pay a death gratuity. Pursuant to 10 U.S.C. 1475–1480, a designated beneficiary (ies) or next-of-kin can receive a death gratuity payment for a deceased service member. This form serves as a record of the disbursement. The DoD Financial Management Regulation (FMR), Volume 7A, Chapter 36, defines the eligible beneficiaries and procedures for payment. To provide internal controls for this benefit, and to comply with the above-cited statutes, the information requested is needed to substantiate the receipt of the benefit.

Affected Public: Individuals or Households.

Annual Burden Hours: 230.5 hours.

Number of Respondents: 461.

Responses Per Respondent: 1.

Average Burden Per Response: 30 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The Service Casualty Office completes the upper portion of the DD Form 397 and provides the form to the beneficiaries. The beneficiaries complete their portion of the form and then sign and have it witnessed. Once the documents are completed, they are forwarded to DFAS for payment.

Dated: July 12, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–17373 Filed 7–18–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2013–OS–0158]

Proposed collection; comment request

AGENCY: National Geospatial-Intelligence Agency, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the National Geospatial-Intelligence Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 17, 2013.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information. Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Polygraph Branch Chief, Security and Installations Division, Personnel Security, National Geospatial-Intelligence Agency, 7500 GEOINT Drive, Springfield, VA 22150.

Title; Associated Form; and OMB Number: National Geospatial-Intelligence Agency Polygraph Records, OMB Control Number 0704–TBD.

Needs and Uses: The information collection requirement is necessary to ensure integrity in the polygraph examination process, document polygraph results, assist with security eligibility determinations and employment or assignment suitability decisions in accordance with applicable laws, regulations and guidance, and to assist with investigations into possible violations of NGA rules and regulations, including the possible loss or compromise of classified or protected NGA information.

Affected Public: Individuals

Annual Burden Hours: 400

Number of Respondents: 2,400

Responses per Respondent: 1

Average Burden per Response: 10 minutes

Frequency: On occasion

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

Respondents are NGA employees, military and contractor personnel who provide personal and professional information to the agency to conduct a polygraph examination. NGA Polygraph Records System is the central system for agency personnel to maintain and, where necessary, disseminate employee information to ensure integrity in the polygraph examination process, document polygraph results, assist with security eligibility determinations and employment or assignment suitability decisions in accordance with applicable laws, regulations and guidance, and to assist with investigations into possible violations of NGA rules and regulations, including the possible loss or compromise of classified or protected NGA information. Without the system, NGA would not be able to perform personnel security activities resulting in not being able to protect agency assets, conduct mission-related activities protecting national security.

Dated: July 11, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–17368 Filed 7–18–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2013–OS–0162]

Proposed Collection; Comment Request

AGENCY: Defense Finance and Accounting Service (DFAS), DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the DFAS announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 17, 2013.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Finance and Accounting Services-Cleveland, 1240 East 9th Street, Cleveland, OH 44199, ATTN: Mr. Charles Moss, *charles.moss@dfas.mil,* 216–204–4426.

Title; Associated Form; and OMB Number: DD Form 2788, Child Annuitant's School Certification, OMB Number 0730–0001.

Needs and Uses: In accordance with 10 U.S.C. 1447 and DoD Financial Management Regulation, 7000.14–R, Volume 7B, a child annuitant between the age of 18 and 22 years of age must provide evidence of intent to continue study or training at a recognized educational institution. The certificate is required for the school semester or other period in which the school year is divided

Affected Public: Individuals

Annual Burden Hours: 7,200 hours

Number of Respondents: 3600

Responses Per Respondent: 2

Average Burden per Response: 1 hour

Frequency: Once each semester of full time school, ages 18 to 22

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The Child Annuitant's School Certification form is submitted to the child for completion and returned to this agency. The child will certify as to his or her intent for future enrollment and a school official must certify on the past or present school enrollment of the child. By not obtaining school certification, overpayment of annuities to children would exist. This information may be collected from some schools which are non-profit institutions such as religious institutions. If information is not received after the end of each school enrollment, over disbursements of an annuity would be made to a child who elected not to continue further training or study.

Dated: July 12, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–17374 Filed 7–18–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2013–OS–0160]

Proposed Collection; Comment Request

AGENCY: Defense Finance and Accounting Service (DFAS), DoD.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the DFAS announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 17, 2013.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Finance and Accounting Services—Columbus, Ohio, 3990 E. Broad Street, Columbus, Ohio 43216, ATTN: Ms. Kenna Robinett, Account Management and Provisioning System (AMPS) Program Manager, Enterprise Systems. Telephone: (614) 701–2451 or Mr. Marcus Ritter, Project Manager, (317–212–6547); and Defense Logistics Agency (DLA), AMPS Program Manager, Mr. Walter B. Gooch, System Manager, Branch Chief, External Solutions, DLA Richmond VA, 8000 Jefferson Davis Highway, Richmond, Virginia 23237. Telephone: (804) 279–3075.

Title; Associated Form; and OMB Number: Account Management and Provisioning System (AMPS); OMB Control Number: 0730–TBD.

Needs and Uses: The information collection requirement is necessary to maintain information for operations to control and track access to secure networks, computer systems, and databases. Records are maintained on electronic storage media. The SSNs are used to allow Non-DoD individuals to create a user account within AMPS, and for AMPS to track those users. Additionally, the SSN is used for systems that limit system rights based on that number. For example, in the Defense Civilian Pay System (DCPS), a user is not allowed to access their pay records, and that is managed through the SSN.

Affected Public: Individuals or Households

Annual Burden Hours: 209 hours

Number of Respondents: 2500

Responses per Respondent: 1

Average Burden per Response: 5 minutes

Frequency: On occasion

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

AMPS does not extract or interface with any other system to obtain PII information for users. All users are required to set-up a user account to use AMPS. AMPS is Common Access Card (CAC) enabled and DoD employees will access AMPS via their CAC. AMPS can extract user data from the Electronic Data Interchange-Personnel Identifier (EDI/PI) to help set-up the user account. Any user that is not issued a CAC will enter their information into AMPS to create a user account, and will be given a user ID and password to access the system.

The following are examples of information collected from users: User names; SSN (for individuals not in possession of a CAC such as newly hired Federal employees); U.S. citizenship status (i.e., U.S. Citizen, Foreign National, other); physical and electronic address; work telephone numbers; organization; office symbol; contractor/employee status; computer logon addresses, passwords, and user identification codes; type of access/permissions required; verification of need to know; dates of mandatory information assurance awareness training; and security clearance data. The system also captures details about programs, databases, functions, and sites accessed and/or used; dates and times of use; and information products created, received, or altered during use. The records may also contain details about access or functionality problems telephoned in for technical support along with resolution. For individuals who telecommute from home or a telework center, the records may contain the electronic address and telephone number at that location. For contractors, the system also contains the company name, contract number, and contract expiration date.

Dated: July 11, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–17376 Filed 7–18–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2013–OS–0090]

Notice of Availability for Sharpe Permit Relinquishment Project Environmental Assessment Finding of No Significant Impact

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice of Availability (NOA) for Sharpe Permit Relinquishment Project Environmental Assessment (EA) Finding of No Significant Impact (FONSI).

SUMMARY: On April 30, 2013, Defense Logistics Agency (DLA) published a NOA in the **Federal Register** (78 FR 25258–25259) announcing the publication of the Sharpe Permit Relinquishment Project EA. The EA was available for a 30-day public comment period which ended May 30, 2013. The EA was prepared as required under the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4331 et seq.). No comments were received during the comment period. This FONSI documents the decision of DLA to relinquish the permit for use and occupancy of the Sharpe Army Depot, currently known as Defense Distribution Depot San Joaquin, California—Sharpe (Sharpe Site) with a determination that no significant impacts on the human environment are associated with this decision.

FOR FURTHER INFORMATION CONTACT: Defense Distribution Depot San Joaquin, California—Sharpe Public Affairs Office, P.O. Box 960001, Stockton, CA 95296–0001, ATTN: Sharpe Permit Relinquishment Project. (209) 839–4226. *DDJCPublicAffairsOffice@dla.mil*.

SUPPLEMENTARY INFORMATION: DLA has occupied the Sharpe Site since 1990 under a Memorandum of Agreement with the U.S. Department of the Army (Army). DLA is proposing to move its operations from the Sharpe Site to its Defense Distribution Depot San Joaquin, California—Tracy (Tracy Site). Currently, DLA has co-existing operations at both facilities. Consolidation of operations at one facility would increase efficiency of DLA operations by reducing redundancies, thereby reducing operational costs.

Purpose and Need for Action: The purpose of the Sharpe Permit Relinquishment Project is to return the land and improvements at the Sharpe Site to the Army as DLA has proposed consolidation of its operations from the Sharpe Site to its nearby Tracy Site.

Consolidation of the operations into one facility increases efficiency of DLA operations and reduces operational costs. The consolidation would not substantially alter other non-DLA operations at the Sharpe site and the federal government will continue ongoing environmental restoration efforts at the Sharpe Site following the permit relinquishment.

Proposed Action and Alternatives: Under the proposed action, DLA would relinquish occupancy and use of the property and return the Sharpe Site to the Army who owns the land and the improvements thereon. DLA wants to consolidate activities currently performed at the Sharpe Site to its existing facilities at the Tracy Site and potentially other DLA facilities. Land and improvements associated with the property would be conveyed back to the Army. The Army would assume all management responsibilities associated with the property. No new construction or ground disturbing activities at the Tracy Site would result from the proposed action. As an alternative to the proposed action, DLA considered taking no action. The no action alternative would have maintained existing conditions through continued occupancy and use of the facility by DLA. Under this alternative, the Army would not resume occupancy and use of the property and DLA would continue to operate the facility until the conclusion of its current permit on April 11, 2020. The no action alternative would not satisfy the project's purpose and need; however, the alternative was included in the environmental analysis to provide a baseline for comparison with the proposed action and was analyzed in accordance with Council on Environmental Quality regulations for implementing NEPA.

An additional alternative was considered, but eliminated from further consideration. This alternative included relocating Sharpe operations to a nearby commercially available site. This alternative was dismissed from further consideration because there would be additional security risks associated with operations conducted at non-secured facilities, as well as additional operational costs.

Potential Environmental Impacts: Potential environmental impacts of the proposed action have been assessed and compared to the impacts of the no action alternative. The proposed action is expected to have the following impacts:

- Minor short-term adverse impacts to air quality, noise, and traffic during the transportation of supplies and materials from the Sharpe Site to other DLA facilities.
- A reduction in traffic at the Sharpe Site, which would lessen potential traffic-related affects to burrowing owls with a long-term negligible beneficial impact on the biological resources at the Sharpe Site.
- A reduction in the work force at the Sharpe Site and an increased work force at the Tracy Site. As such, there would be a long-term negligible adverse impact on the socioeconomic resources on the local Lathrop area and a long-term negligible beneficial impact on the socioeconomic resources on the local Tracy area.
- A temporary increase in economic activities resulting in a short-term and negligible economic beneficial impact for the local economies.

Determination: DLA has determined that implementation of the proposed action will not have a significant effect on the human environment. Human environment was interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment. Specifically, no highly uncertain or controversial impacts, unique or unknown risks, or cumulatively significant effects were identified. Implementation of the proposed action will not result in the loss or destruction of significant scientific, cultural, or historic resources and implementation of the proposed action will not violate any federal, state, or local laws. Based on the results of the analyses performed during the preparation of the environmental assessment, David Rodriquez, Director, DLA Installation Support, concludes the proposed action to relinquish the permit to use and occupy the Sharpe site does not constitute a major federal action significantly affecting the quality of the human environment within the context of the NEPA. Therefore, an environmental impact statement for the proposed action is not required.

Dated: July 16, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–17377 Filed 7–18–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Business Board; Notice of Federal Advisory Committee Meeting

AGENCY: DoD.

ACTION: Meeting notice; cancellation.

SUMMARY: On Tuesday, July 9, 2013 (78 FR 41042), the Department of Defense published a notice announcing a July 25, 2013 meeting of the Defense Business Board. This notice announces that the Defense Business Board meeting scheduled for Thursday, July 25, 2013 is hereby cancelled. The Board will not have any completed studies to outbrief and deliberate on. Therefore, to conserve financial resources, the meeting is cancelled. The next Quarterly Board Meeting will be held on October 17, 2013.

FOR FURTHER INFORMATION CONTACT: Ms. Phyllis Ferguson, *Phyllis.Ferguson@osd.mil,* 703–695–7563 or Ms. Debora Duffy, *Debora.Duffy@osd.mil,* (703) 697–2168.

Dated: July 16, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–17369 Filed 7–18–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the National Commission on the Structure of the Air Force

AGENCY: Director of Administration and Management, DoD.

ACTION: Notice of Advisory Committee Meeting.

SUMMARY: Under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150, the Department of Defense (DoD) announces that the following Federal advisory committee meeting of the National Commission on the Structure of the Air Force (''the Commission'') will take place.

DATES: *Date of Closed Meeting, including Hearing and Commission Discussion:* Monday, July 22, 2013.

ADDRESSES: 2521 South Clark Street, Suite 525, Crystal City, VA 22202, from 8:30 a.m. to 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: Mrs. Marcia Moore, Designated Federal Officer, National Commission on the Structure of the Air Force, 1950 Defense Pentagon Room 3A874, Washington, DC 20301–1950. Email: *dfoafstrucomm@osd.mil.* Desk (703) 545–9113. Facsimile (703) 692–5625.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: The members of the Commission will hear testimony from individual witnesses and then will discuss the information presented at the hearings.

Agenda

July 22, 2013—Closed Meeting, Including Hearing and Commission Discussion: DoD speakers will provide classified information on the roles, missions and capabilities of the various DoD components and how they contribute to the national defense strategy, the integration of force requirements, and DoD's strategies and capabilities to address conflicts and threats. Confirmed speakers include: Mr. David Ochmanek, Deputy Assistant Secretary of Defense for Force Development, Office of the Secretary of Defense; and Major General Timothy Ray, U.S. Air Force, Director, Operational Planning, Policy and Strategy, Deputy Chief of Staff, Operations, Plans and Requirements, Headquarters, U.S. Air Force, Vice Admiral Kurt Tidd, Director of Operations, Joint Chiefs of Staff, and Major General James McLaughlin, Commander, 24th Air Force and Commander, Air Forces Cyber, Joint Base San Antonio—Lackland, Texas. Specific agenda topics include:

1. The translation of deploy-to-dwell rates into the percentage of the force, by component, when actually deployed.
2. The differences among the components in their ability to plan and generate forces.
3. The long term demand for rotational forces.
4. Assessment of the non-warplan-driven requirement for the reserve forces.
5. The Department's use of the Joint Operational Planning and Execution System and the current and future operations plans of the Combatant Commanders.
6. As a follow up to the Commissioner's interest in how well the active, reserve, and Guard forces manage their joint capabilities in the use of and response to cyber warfare, General McLaughlin will brief the Commissioners on its mission.

Meeting Accessibility: In accordance with section 10(d) of the FACA, 5 U.S.C. 552b, and 41 CFR 102–3.155, the DoD has determined that the meeting scheduled for July 22, 2013 will be closed to the public. Specifically, the Director of Administration and Management, with the coordination of the DoD FACA Attorney, has determined in writing that this portion of the meeting will be closed to the public because it will discuss classified information and matters covered by 5 U.S.C. 552b(c)(1).

Written Comments: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the FACA, the public or interested organizations may submit written comments to the Commission in response to the stated agenda of the closed meeting or the Commission's mission. The Designated Federal Officer (DFO) will review all submitted written statements. Written comments should be submitted to Mrs. Marcia Moore, DFO, via facsimile or electronic mail, the preferred modes of submission. Each page of the comment must include the author's name, title or affiliation, address, and daytime phone number. The DFO will ensure that the written statements are provided to the membership for their consideration. All contact information may be found in **FOR FURTHER INFORMATION CONTACT.** Due to difficulties finalizing the meeting agenda and obtaining the required statutory determinations to approve closing the scheduled meeting of July 22, 2013, to the public for the National Commission on the Structure of the Air Force the requirements of 41 CFR 102–3.150(a) were not met. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Background

The National Commission on the Structure of the Air Force was established by the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239). The Department of Defense sponsor for the Commission is the Director of Administration and Management. The Commission is tasked to submit a report, containing a comprehensive study and recommendations, by February 1, 2014 to the President of the United States and the Congressional defense committees. The report will contain a detailed statement of the findings and conclusions of the Commission, together with its recommendations for such legislation and administrative actions it may consider appropriate in light of the results of the study. The comprehensive study of the structure of the U.S. Air Force will determine whether, and how, the structure should be modified to best fulfill current and anticipated mission requirements for the U.S. Air Force in a manner consistent with available resources.

The evaluation factors under consideration by the Commission are for a U.S. Air Force structure that—(a) Meets current and anticipated requirements of the combatant commands; (b) achieves an appropriate balance between the regular and reserve components of the Air Force, taking advantage of the unique strengths and capabilities of each; (c) ensures that the regular and reserve components of the Air Force have the capacity needed to support current and anticipated homeland defense and disaster assistance missions in the United States; (d) provides for sufficient numbers of regular members of the Air Force to provide a base of trained personnel from which the personnel of the reserve components of the Air Force could be recruited; (e) maintains a peacetime rotation force to support operational tempo goals of 1:2 for regular members of the Air Forces and 1:5 for members of the reserve components of the Air Force; and (f) maximizes and appropriately balances affordability, efficiency, effectiveness, capability, and readiness.

Dated: July 16, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–17402 Filed 7–18–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2013–0031]

Proposed Collection; Comment Request

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Department of the Navy announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 17, 2013.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Marine Corps Marathon Office, Attn: Angela Huff, P.O. Box 188, Quantico, VA 22134, or call the Marine Corps Marathon Office at (703) 432–1159.

Title; Associated Form; and OMB Number: Marine Corps Marathon Race Applications; OMB Control Number 0703–0053.

Needs and Uses: The information collection requirement is necessary to obtain and record the information of runners to conduct the races, for timing purposes and for statistical use.

Affected Public: Individuals or households.

Annual Burden Hours: 5,283.

Marine Corps Marathon—5 min burden.

Burden hours: 30,000 runners × 5 min = 144,240 min = 2,404 hours.

Healthy Kids Fun Run—5 min burden.

Burden hours: 3,600 runners × 5 min = 18,000 min = 300 hours.

Marine Corps Marathon 10K—5 min burden.

Burden hours: 10,000 runners × 5 min = 50,000 min = 833.33 hours.

Marine Corps Historic Half—5 min burden.

Burden hours: 8,000 runners × 5 min = 40,000 min = 666.67 hours.

Semper Fred 5k—5 min burden.

Burden hours: 1,500 runners × 5 min = 7,500 min = 125 hours.

Marine Corps Historic Half 10k—5 min burden.

Burden hours: 1,000 runners × 5 min = 5,000 min = 50 hours.

Marine Corps Marathon Race Series to include MCM 1775, Run Amuck, Crossroads 4 Miler and Turkey Trot—5 min burden.

Burden hours: 9,000 runners × 5 min = 45,000 min = 750 hours.

Marine Corps Marathon Triathlon—5 min burden.

Burden hours: 300 runners × 5 min = 1,500 min = 25 hours.

Number of Respondents: 63,400.

Responses per Respondent: 1.

Average Burden per Response: 5 minutes.

Frequency: Annually.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

Respondents are runners who are signing up for the Marine Corps Marathon races held by the Marine Corps Marathon office, Marine Corps Base Quantico. The seven races defined under OMB number 0703–0053 are the Marine Corps Marathon, the Marine Corps Marathon 10K, and the Marine Corps Marathon Healthy Kids Fun Run, Marine Corps Historic Half, Semper Fred 5K, Marine Corps Marathon Race Series to include Marine Corps 17.75K (former Run 2 Register), Run Amuck, Run Stock and Crossroads 4 miler (former 12K/5K). The additional races to be added to the OMB number are the Marine Corps Historic Half 10K, the Crossroads 4 miler, and Quantico Triathlon. The Marine Corps Marathon office records all runners to conduct the races in preparation and execution of the races and to record statistical information for sponsors, media and for economic impact studies. Collecting this data of the runners is essential for putting on the races.

Dated: July 11, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–17400 Filed 7–18–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC13–18–000; FERC–547]

Commission Information Collection Activities; Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–547 (Gas Pipeline Rates: Refund Report Requirements).

DATES: Comments on the collection of information are due September 17, 2013.

ADDRESSES: You may submit comments (identified by Docket No. IC13–18–000) by either of the following methods:

• *eFiling at Commission's Web site: http://www.ferc.gov/docs-filing/efiling.asp.*

• *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov*, telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: Gas Pipeline Rates: Refund Report Requirements.

OMB Control No.: 1902–0084.

Type of Request: Three-year extension of the FERC–547 information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission uses FERC–547 (Gas Pipeline Rates: Refund Report Requirements) to implement the

statutory refund provisions governed by Sections 4, 5 and 16 of the Natural Gas Act (NGA).[1] Sections 4 and 5 authorize the Commission to order a refund (with interest) for any portion of a natural gas company's increased rate or charge found to be unjust or unreasonable. Refunds may also be instituted by a natural gas company as a stipulation to a Commission-approved settlement agreement or a provision under the company's tariff. Section 16 of the NGA authorizes the Commission to prescribe rules and regulations necessary to administer its refund mandates. The Commission's refund reporting requirements are located in 18 CFR 154.501 and 154.502.

The Commission uses the data to monitor refunds owed by natural gas companies to ensure that the flow-through of refunds owed by these companies are made as expeditiously as possible and to assure that refunds are made in compliance with the Commission's regulations.

Type of Respondents: Natural gas companies.

Estimate of Annual Burden:[2] The Commission reduces its estimate of the total Public Reporting Burden for this information collection from the estimate made three years ago based on the number of filings received over the previous three years (from an average of 30 respondents to an average of 11 respondents currently).

FERC–547: GAS PIPELINE RATES: REFUND REPORT REQUIREMENTS

	Number of respondents	Number of responses per respondent	Total number of responses	Average burden hours per response	Estimated total annual burden
	(A)	(B)	(A) × (B) = (C)	(D)	(C) × (D)
Natural Gas Companies	11	1	11	75	825

The total estimated annual cost burden to respondents is $57,750. [825 hours * $70/hour[3] = $57,750].

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 12, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–17286 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2381–063]

PacifiCorp, St. Anthony Hydro LLC; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Types of Application:* Application for Partial Transfer and Amendment of License.

b. *Project No.:* 2381–063.

c. *Date Filed:* June 11, 2013.

d. *Applicants:* PacifiCorp (transferor) and St. Anthony Hydro LLC (transferee).

e. *Name of Project:* Ashton-St. Anthony Project.

f. *Location:* On the Henry's Fork of the Snake River, in Fremont County, Idaho.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicants Contact:* Mr. John P. Sample, Assistant General Counsel, PacifiCorp, 825 NE Multnomah Street, Suite 1500, Portland, OR 97232–2135, (503) 813–6688, *john.sample@pacificorp.com.*

Mr. Ted S. Sorenson, Member, St. Anthony Hydro LLC, 5203 South 11th East, Idaho Falls, ID 83404, (208) 522–8069, *ted@tsorenson.net.*

i. *FERC Contact:* Mr. Jeremy Jessup, (202) 502–6779, *Jeremy.Jessup@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests, is 30 days from the issuance date of this notice by the Commission. All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments.

Please include the project number (P–2381–063) on any comments, motions, or recommendations filed.

k. *Description of Request:* The applicants request to transfer the St. Anthony development from PacifiCorp to St. Anthony Hydro LLC. PacifiCorp also requests that the Commission amend the license for Project No. 2381 effective upon the partial transfer of license from PacifiCorp to St. Anthony Hydro LLC, to delete all references in the license to the St. Anthony development and remove it from the project boundary. Upon completion of the partial transfer of the license to St. Anthony Hydro LLC, the applicants request that FERC re-designate the St. Anthony development with a new project number.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the

[1] 15 U.S.C. 717–717w.

[2] The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

[3] FY2013 Estimated Average Hourly Cost per FTE, including salary + benefits.

document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All motions to intervene, protests, or comments should relate to project works which are the subject of the application. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: July 12, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–17287 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7320–042]

Erie Boulevard Hydropower, L.P.; Notice of Application Tendered for Filing With the Commission, Soliciting Additional Study Requests, and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 7320–042.

c. *Date Filed:* July 1, 2013.

d. *Applicant:* Erie Boulevard Hydropower, L.P.

e. *Name of Project:* Chasm Hydroelectric Project.

f. *Location:* On the Salmon River, in Franklin County, New York. No federal lands are occupied by the project works or located within the project boundary.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C .791 (a)–825(r).

h. *Applicant Contact:* Steven Murphy, Compliance Specialist, Brookfield Renewable Power—New York West Operations, 33 West 1st Street South, Fulton, NY, 13069; (315) 589–6130; email—*steven.murphy@brookfieldpower.com.*

i. *FERC Contact:* John Mudre at (202) 502–8902; or email at *john.mudre@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* August 30, 2013.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and five copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

m. This application is not ready for environmental analysis at this time.

n. The existing Chasm Project consists of: (1) A 201-foot-long, 32-foot-high maximum height concrete gravity-type dam having a spillway section with crest elevation 1,283.8 feet mean sea level (msl). about 100 feet long, surmounted by 2-foot-high flashboards and having an intake section with steel trash racks and headgates; (2) a reservoir having a surface area of about 22 acres and a gross storage capacity of 74 acre-feet at normal pool elevation of 1,285.8 feet msl; (3) a 7-foot-diameter welded steel pipeline approximately 3,355 feet in length connecting to a 6-foot-diameter steel manifold pipeline just upstream of the powerhouse; (4) a powerhouse containing three Francis-type generating units having a total rated capacity of 3,350 kilowatts operated under a 268-foot head and at a flow of 195 cubic feet per second; (5) a 20-foot-wide, 850-foot-long tailrace; (6) a 4.2-megavolt ampere, 2.4/34.5-kilovolt (kV) transformer; (7) a 410-foot-long, 34.5-kV transmission line; and (8) appurtenant facilities.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural schedule and final amendments:* The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate.

Issue Notice of Acceptance	August 2013.
Issue Scoping Document 1 for comments.	September 2013.
Scoping Meetings and Environmental Site Review.	October 2013.
Comments on Scoping Document 1.	November 2013.
Issue Scoping Document 2	December 2003.
Issue Additional Information Request (if needed).	December 2013.
Issue notice of ready for environmental analysis.	January 2014.
Commission issues draft EA	May 2014.
Comments on draft EA due	June 2014.
Commission issues final EA	October 2014.

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: July 12, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–17288 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13102–003]

Birch Power Company; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Major License (5 Megawatts or less).

b. *Project No.:* 13102–003.

c. *Date filed:* July 2, 2013.

d. *Applicant:* Birch Power Company.

e. *Name of Project:* Demopolis Lock and Dam Hydroelectric Project.

f. *Location:* At the U.S. Army Corps of Engineers' Demopolis Lock and Dam, on the Tombigbee River, west of the city of Demopolis in Marengo and Sumter Counties, Alabama. Lands managed by the Federal government are located within the project boundary.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Nicholas E. Josten, GeoSense, 2742 Saint Charles Ave, Idaho Falls, ID 83404, (208) 528–6152.

i. *FERC Contact:* Michael Spencer, (202) 502–6093, *michael.spencer@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* September 2, 2013.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and five copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

m. The application is not ready for environmental analysis at this time.

n. The proposed project would utilize the existing U.S. Army Corps of Engineers' Demopolis Lock and Dam and Reservoir, and would consist of the following new facilities: (1) A 900-foot-long intake channel; (2) a powerhouse adjacent to the north end of the existing dam containing two turbine-generator units for a total installed capacity of 48,000 kilowatts; (3) a 200-foot-long tailrace channel; and (4) a 4.4 mile-long 115 kilo-Volt transmission line. The project is estimated to generate an average of 213,000 megawatt-hours annually.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. With this notice, we are initiating consultation with the Alabama State Historic Preservation Officer (SHPO), as required by section 106 of the National Historic Preservation Act and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

q. *Procedural schedule:* The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate.

Issue Notice of Acceptance	October 2013.
Issue Scoping Document 1 for comments.	November 2013.
Comments on Scoping Document 1.	December 2013.
Issue Scoping Document 2	February 2014.
Issue notice of ready for environmental analysis.	February 2014.
Commission issues EA, draft EA, or draft EIS.	August 2014.
Comments on EA or draft EA or draft EIS.	September 2014.

Commission issues final EA or final EIS.	November 2014.

Dated: July 11, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–17289 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP13–509–000]

DCP Midstream, LP; Notice of Application

Take notice that on July 1, 2013, DCP Midstream, LP (DCP), filed an application pursuant to Section 7(c) of the Natural Gas Act and Part 157 of the Commission's Regulations, for a limited certificate authorizing DCP to construct and operate a 7.6-mile, 16-inch diameter pipeline located in Weld County, Colorado, (the Lucerne Residue Pipeline). The Lucerne Residue Pipeline will connect DCP's new non-jurisdictional natural gas processing facilities (Lucerne II Gas Plant) with the interstate natural gas pipeline system. DCP requests for waivers of certain of the Commission's rate, tariff and accounting regulatory requirements regarding the proposed Lucerne Residue Pipeline. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@gerc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

DCP is a non-jurisdictional gas gathering company having facilities in Texas, Oklahoma, New Mexico, Louisiana, Colorado, Kansas, Arkansas, and Wyoming. DCP generally operates these facilities to deliver raw gas to processing plants. To address the new development of Niobrara Shale in the Denver-Julesburg Basin (DJ Basin), DCP proposes to construct the Lucerne Residue Pipeline connecting Lucerne II Gas Plant with an interstate pipeline, Colorado Interstate Gas Company (CIG). The Lucerne Residue Pipeline has a design capacity of 230 MMcf/day and will be used for transportation of natural gas solely on behalf of DCP without payment of any additional charge for the service. DCP does not intend to transport gas through the Lucerne Residue Pipeline for shippers other than DCP. The pipeline will be constructed entirely inside DCP's right of way and costs about $12 million.

Any questions regarding this application should be directed to Katie Rice, Director, Regulatory Affairs, DCP Midstream, LP, 370 17th Street, Suite 2500, Denver, Colorado 80202. Telephone 303–605–2166, fax 303–605–2226, and email: *kerice@dcpmidstream.com.*

Pursuant to Section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 5 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Motions to intervene, protests and comments may be filed electronically via the internet in lieu of paper; see, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Comment Date: August 2, 2013.

Dated: July 12, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–17291 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC13–128–000.

Applicants: Silver Merger Sub, Inc., Nevada Power Company, Sierra Pacific Power Company, NV Energy, Inc.

Description: Joint Application for Authorization under Section 203 of the Federal Power Act of Silver Merger Sub, Inc., et. al.

Filed Date: 7/12/13.

Accession Number: 20130712–5087.

Comments Due: 5 p.m. e.t. 9/10/13.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–3212–001; ER11–3213–001; ER11–3214–001; ER13–1855–001.

Applicants: XO Energy NY, LP, XO Energy MA, LP, XO Energy MW, LP, XO Energy SW., LP.

Description: Notice of Non-Material Change in Status of XO Energy Companies under ER11–3213–000, et. al.

Filed Date: 7/12/13.

Accession Number: 20130712–5122.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1673–000.

Applicants: Entergy Arkansas, Inc.

Description: Entergy Arkansas, Inc. submits tariff filing per 35.19a(b): Compliance Refund Report to be effective N/A.

Filed Date: 7/12/13.

Accession Number: 20130712–5074.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1674–000.

Applicants: Entergy Gulf States Louisiana, L.L.C.

Description: Entergy Gulf States Louisiana, L.L.C. submits tariff filing per 35.19a(b): Compliance Refund Report to be effective N/A.

Filed Date: 7/12/13.

Accession Number: 20130712–5091.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1675–000.

Applicants: Entergy Louisiana, LLC.

Description: Entergy Louisiana, LLC submits tariff filing per 35.19a(b): Compliance Refund Report to be effective N/A.

Filed Date: 7/12/13.

Accession Number: 20130712–5094.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1676–000.

Applicants: Entergy Mississippi, Inc.

Description: Entergy Mississippi, Inc. submits tariff filing per 35.19a(b): Compliance Refund Report to be effective N/A.

Filed Date: 7/12/13.

Accession Number: 20130712–5096.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1677–000.

Applicants: Entergy New Orleans, Inc.

Description: Entergy New Orleans, Inc. submits tariff filing per 35.19a(b): Compliance Refund Report to be effective N/A.

Filed Date: 7/12/13.

Accession Number: 20130712–5097.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1678–000.

Applicants: Entergy Texas, Inc.

Description: Entergy Texas, Inc. submits tariff filing per 35.19a(b): Compliance Refund Report to be effective N/A.

Filed Date: 7/12/13.

Accession Number: 20130712–5098.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1964–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Queue Position W1–108; Original Service Agreement No. 3590 to be effective 6/12/2013.

Filed Date: 7/12/13.

Accession Number: 20130712–5124.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1965–000.

Applicants: NRG Wholesale Generation LP.

Description: NRG Wholesale Generation LP submits tariff filing per 35: Notice of Succession—MBR to be effective 7/15/2013.

Filed Date: 7/12/13.

Accession Number: 20130712–5129.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1966–000.

Applicants: NRG Wholesale Generation LP.

Description: NRG Wholesale Generation LP submits tariff filing per 35: Notice of Succession—3 to be effective 7/15/2013.

Filed Date: 7/12/13.

Accession Number: 20130712–5130.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1967–000.

Applicants: NRG Wholesale Generation LP.

Description: NRG Wholesale Generation LP submits tariff filing per 35: Notice of Succession—5 to be effective 7/15/2013.

Filed Date: 7/12/13.

Accession Number: 20130712–5131.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1968–000.

Applicants: NRG Wholesale Generation LP.

Description: NRG Wholesale Generation LP submits tariff filing per 35: Notice of Succession—7 to be effective 7/15/2013.

Filed Date: 7/12/13.

Accession Number: 20130712–5132.

Comments Due: 5 p.m. e.t. 8/2/13.

Docket Numbers: ER13–1969–000.

Applicants: NRG Wholesale Generation LP.

Description: NRG Wholesale Generation LP submits tariff filing per 35: Notice of Succession—8 to be effective 7/15/2013.

Filed Date: 7/12/13.

Accession Number: 20130712–5134.

Comments Due: 5 p.m. e.t. 8/2/13.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11–29–002.

Applicants: Entergy Texas, Inc.

Description: Supplement to April 30, 2013 Application of Entergy Texas, Inc., for extension of FPA Section 204 authorization.

Filed Date: 7/12/13.

Accession Number: 20130712–5075.

Comments Due: 5 p.m. e.t. 7/22/13.

Docket Numbers: ES13–35–000.

Applicants: AEP West Virginia Transmission Company,

Description: Application under Section 204 of the Federal Power Act for authorization to issue securities of AEP West Virginia Transmission Company, Inc.

Filed Date: 7/12/13.

Accession Number: 20130712–5067.

Comments Due: 5 p.m. e.t. 8/2/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 12, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–17334 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC13–127–000.

Applicants: Astoria Energy II LLC.

Description: Application under FPA Section 203 of Astoria Energy II LLC.

Filed Date: 7/11/13.

Accession Number: 20130711–5154.

Comments Due: 5 p.m. ET 8/1/13.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–1274–001.
Applicants: California Independent System Operator Corporation.
Description: 2013–07–11_Bucket Compliance to be effective 4/15/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5142.
Comments Due: 5 p.m. ET 8/1/13.
Docket Numbers: ER13–1958–000.
Applicants: FirstEnergy Service Company.
Description: Petition of FirstEnergy Service Company for Limited Waiver of the PJM Interconnection, L.L.C. Open Access Transmission Tariff and Request for Action by August 23, 2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5124.
Comments Due: 5 p.m. ET 8/1/13.
Docket Numbers: ER13–1959–000.
Applicants: Niagara Mohawk Power Corporation.
Description: Notice of Cancellation of Rate Schedule No. 180 Transportation Services Agreement with the New York Power Authority of Niagara Mohawk Power Corporation.
Filed Date: 7/11/13.
Accession Number: 20130711–5127.
Comments Due: 5 p.m. ET 8/1/13.
Docket Numbers: ER13–1961–000.
Applicants: Northern States Power Company, a Minnesota corporation.
Description: 2013–7–11_NSP_UND_R&R Trans&TrsfmrAgrmt_440_0.0.0 to be effective 1/1/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5143.
Comments Due: 5 p.m. ET 8/1/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 11, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–17335 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–1909–000.
Applicants: Maine Public Service Company.
Description: MPS Order No. 1000 Interregional Compliance Filing to be effective N/A.
Filed Date: 7/9/13.
Accession Number: 20130709–5035.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1923–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 07–10–13 MISO–SERTP Order 1000 Interregional to be effective 1/1/2015.
Filed Date: 7/10/13.
Accession Number: 20130710–5092.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1924–000.
Applicants: Duquesne Light Company, PJM Interconnection, L.L.C.
Description: PJM TOs OATT Order No. 1000 Compliance Filing re MISO–PJM JOA to be effective N/A.
Filed Date: 7/10/13.
Accession Number: 20130710–5093.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1926–000.
Applicants: Duquesne Light Company, PJM Interconnection, L.L.C.
Description: PJM TOs Cost Allocation Revisions to NYISO–PJM JOA Order 1000 Compliance to be effective N/A.
Filed Date: 7/10/13.
Accession Number: 20130710–5106.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1927–000.
Applicants: Duquesne Light Company, PJM Interconnection, L.L.C.
Description: PJM Transmission Owners file PJM OATT Revisions re PJM–SERTP Cost Allocation to be effective 1/1/2014.
Filed Date: 7/10/13.
Accession Number: 20130710–5111.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1928–000.
Applicants: Duke Energy Progress, Inc., Duke Energy Carolinas, LLC.
Description: Order No. 1000 Interregional Compliance Filing—Carolinas to be effective 12/31/9998.
Filed Date: 7/10/13.
Accession Number: 20130710–5116.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1930–000.
Applicants: Louisville Gas and Electric Company.
Description: Order No. 1000 Compliance Filing to be effective 12/31/9998.
Filed Date: 7/10/13.
Accession Number: 20130710–5127.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1935–000.
Applicants: South Carolina Electric & Gas Company.
Description: Order 1000 Interregional filing to be effective 12/31/9998.
Filed Date: 7/10/13.
Accession Number: 20130710–5176.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1936–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM OATT Order No. 1000 Interregional Compliance Filing re OA Schedule 6 & 6A to be effective 1/1/2014.
Filed Date: 7/10/13.
Accession Number: 20130710–5181.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1937–000.
Applicants: Southwest Power Pool, Inc.
Description: Order No. 1000 Interregional Compliance Joint Operating Agreement with MISO to be effective 12/31/9998.
Filed Date: 7/10/13.
Accession Number: 20130710–5187.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1938–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 07–10–13 MISO–SPP Order 1000 Interregional to be effective 3/30/2014.
Filed Date: 7/10/13.
Accession Number: 20130710–5192.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1939–000.
Applicants: Southwest Power Pool, Inc.
Description: Order 1000 Interregional Compliance Filing to be effective 12/31/9998.
Filed Date: 7/10/13.
Accession Number: 20130710–5193.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1940–000.
Applicants: Ohio Valley Electric Corporation.
Description: Order No. 1000 Compliance Filing to be effective 12/31/9998.
Filed Date: 7/10/13.
Accession Number: 20130710–5199.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1941–000.
Applicants: Alabama Power Company.
Description: Order No. 1000 Interregional Compliance Filing—

FILING SUMBITTED UNDER PROTEST to be effective 12/31/9998.

Filed Date: 7/10/13.

Accession Number: 20130710–5200.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1942–000.

Applicants: New York Independent System Operator, Inc.

Description: OATT Order No. 1000 Compliance Filing to be effective 1/1/2014.

Filed Date: 7/10/13.

Accession Number: 20130710–5222.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1943–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: 07–10–13 MISO–PJM Order 1000 Interregional to be effective 9/17/2010.

Filed Date: 7/10/13.

Accession Number: 20130710–5231.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1944–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM OATT Order 1000 Interregional Compliance filing re the PJM–MISO JOA to be effective 1/1/2014.

Filed Date: 7/10/13.

Accession Number: 20130710–5237.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1945–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: 07–10–13 Order 1000 Interregional Att FF to be effective 1/1/2014.

Filed Date: 7/10/13.

Accession Number: 20130710–5238.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1946–000.

Applicants: New York Independent System Operator, Inc.

Description: OATT Order No. 1000 Compliance Filing to be effective 7/10/2013.

Filed Date: 7/10/13.

Accession Number: 20130710–5240.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1947–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM OATT Order No. 1000 Compliance Filing re NYISO–PJM JOA to be effective 7/10/2013.

Filed Date: 7/10/13.

Accession Number: 20130710–5241.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1955–000.

Applicants: Entergy Services, Inc.

Description: Entergy Services, Inc. submits OATT Order No. 1000 Interregional Coordination Compliance Filing and Limited Waiver Request.

Filed Date: 7/10/13.

Accession Number: 20130710–5259.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1956–000.

Applicants: Cleco Power LLC.

Description: Cleco Power LLC submits Order No. 1000 Interregional Compliance Filing.

Filed Date: 7/10/13.

Accession Number: 20130710–5264.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1957–000.

Applicants: ISO New England Inc., PJM Interconnection, L.L.C., New York Independent System Operator, Inc.

Description: Northeastern ISO/RTO Planning Coordination Protocol Agreement to be effective 7/10/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5119.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1960–000.

Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: Interregional Coordination and Cost Allocation Order 1000 to be effective 1/1/2014.

Filed Date: 7/11/13.

Accession Number: 20130711–5133.

Comments Due: 5 p.m. ET 8/26/13.

Docket Numbers: ER13–1962–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 07–11–2013 SA 6502 Ameren-MISO SSR Agreement to be effective 1/1/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5178.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1963–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 07–11–2013 Schedule 43C Ameren Edwards to be effective 1/1/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5189.

Comments Due: 5 p.m. ET 7/31/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

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Dated: July 12, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–17336 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC13–125–000.

Applicants: CalPeak Power LLC, CalPeak Power—Border LLC, CalPeak Power—Panoche LLC, CalPeak Power—Vaca Dixon LLC, CalPeak Power—Enterprise LLC.

Description: Application of CalPeak Power, LLC, et al. for Authorization under Section 203 of the Federal Power Act for Disposition of Jurisdictional Facilities and Requests for Expedited Consideration and Confidential Treatment.

Filed Date: 7/10/13.

Accession Number: 20130710–5255.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: EC13–126–000.

Applicants: Starwood Power-Midway, LLC.

Description: Application of Starwood Power-Midway, LLC for Authorization under Section 203 of the Federal Power Act for Disposition of Jurisdictional Facilities and Requests for Expedited Consideration and Confidential Treatment.

Filed Date: 7/10/13.

Accession Number: 20130710–5257.

Comments Due: 5 p.m. ET 7/31/13.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–1858–002; ER11–1859–001.

Applicants: NorthWestern Corporation, Montana Generation, LLC.

Description: NorthWestern Corporation, et al. submits an updated market power screen analysis for wholesale electricity markets in the Northwest Region.

Filed Date: 7/1/13.

Accession Number: 20130703–0016.

Comments Due: 5 p.m. ET 8/30/13.

Docket Numbers: ER13–1943–001.

Applicants: Midcontinent Independent System Operator, Inc.
Description: 07–10–13 to be effective 1/1/2014.
Filed Date: 7/11/13.
Accession Number: 20130711–5000.
Comments Due: 5 p.m. ET 8/26/13.
Docket Numbers: ER13–1948–000.
Applicants: Southern California Edison Company.
Description: GIA and Distribution Service Agmt with Searles Valley Minerals to be effective 7/13/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5001.
Comments Due: 5 p.m. ET 8/1/13.
Docket Numbers: ER13–1949–000.
Applicants: Southern California Edison Company.
Description: Amended Distribution Service Agreement with Cascade Solar to be effective 6/1/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5002.
Comments Due: 5 p.m. ET 8/1/13.
Docket Numbers: ER13–1950–000.
Applicants: Southern California Edison Company.
Description: Amended Distribution Service Agreement with City of Banning-Devers-Mirage Split to be effective 6/1/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5003.
Comments Due: 5 p.m. ET 8/1/13.
Docket Numbers: ER13–1951–000.
Applicants: Niagara Mohawk Power Corporation.
Description: Notice of Cancellation of Interconnection Agreement with Indeck-Yerkes Limited Partnership of Niagara Mohawk Power Corporation.
Filed Date: 7/10/13.
Accession Number: 20130710–5251.
Comments Due: 5 p.m. ET 7/31/13.
Docket Numbers: ER13–1952–000.
Applicants: Niagara Mohawk Power Corporation.
Description: Notice of Cancellation of Interconnection Agreement with Indeck-Olean Limited Partnership of Niagara Mohawk Power Corporation.
Filed Date: 7/10/13.
Accession Number: 20130710–5252.
Comments Due: 5 p.m. ET 7/31/13.
Docket Numbers: ER13–1953–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Midcontinent Independent System Operator, Inc. submits 07–11–2013 BREC–KU T–T IA Cert of Concur to be effective 9/3/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5042.
Comments Due: 5 p.m. ET 8/1/13.
Docket Numbers: ER13–1954–000.
Applicants: Aragonne Wind LLC.
Description: Request for Waiver of Tariff Provision by Aragonne Wind LLC under ER13–1954.
Filed Date: 7/10/13.
Accession Number: 20130710–5253.
Comments Due: 5 p.m. ET 7/31/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

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Dated: July 11, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–17333 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP13–1051–000.
Applicants: Questar Pipeline Company.
Description: QPC cleanup to be effective 8/10/2013.
Filed Date: 7/10/13.
Accession Number: 20130710–5126.
Comments Due: 5 p.m. ET 7/22/13.
Docket Numbers: RP13–1052–000.
Applicants: Mississippi Hub, LLC.
Description: Mississippi Hub, LLC ACA Tariff Update July 2013_2 to be effective 10/1/2013.
Filed Date: 7/10/13.
Accession Number: 20130710–5148.
Comments Due: 5 p.m. ET 7/22/13.
Docket Numbers: RP13–1053–000.
Applicants: Texas Eastern Transmission, LP.
Description: Range 8929199 7–11–2013 Negotiated Rate to be effective 7/11/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5028.
Comments Due: 5 p.m. ET 7/23/13.
Docket Numbers: RP13–1054–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5029.
Comments Due: 5 p.m. ET 7/23/13.
Docket Numbers: RP13–1055–000.
Applicants: Big Sandy Pipeline, LLC.
Description: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5032.
Comments Due: 5 p.m. ET 7/23/13.
Docket Numbers: RP13–1056–000.
Applicants: Bobcat Gas Storage.
Description: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5033.
Comments Due: 5 p.m. ET 7/23/13.
Docket Numbers: RP13–1057–000.
Applicants: Egan Hub Storage, LLC.
Description: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5034.
Comments Due: 5 p.m. ET 7/23/13.
Docket Numbers: RP13–1058–000.
Applicants: East Tennessee Natural Gas, LLC.
Description: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5039.
Comments Due: 5 p.m. ET 7/23/13.
Docket Numbers: RP13–1059–000.
Applicants: Gulfstream Natural Gas System, L.L.C.
Description: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.
Filed Date: 7/11/13.
Accession Number: 20130711–5040.
Comments Due: 5 p.m. ET 7/23/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 11, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–17306 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–1065–000.

Applicants: Northern States Power Company, a Minnesota corporation.

Description: 2013–7–9–CAPX–CMA–BRKGS-Refund Report to be effective N/A.

Filed Date: 7/9/13.

Accession Number: 20130709–5136.

Comments Due: 5 p.m. ET 7/30/13.

Docket Numbers: ER13–1066–000.

Applicants: Northern States Power Company, a Minnesota corporation.

Description: 2013–7–9–CAPX–BRKGS–OMA-Refund Report to be effective N/A.

Filed Date: 7/9/13.

Accession Number: 20130709–5138.

Comments Due: 5 p.m. ET 7/30/13.

Docket Numbers: ER13–1067–000.

Applicants: Northern States Power Company, a Minnesota corporation.

Description: 2013–7–9–CAPX–BRKGS–TCEA-Refund Report to be effective N/A.

Filed Date: 7/9/13.

Accession Number: 20130709–5139.

Comments Due: 5 p.m. ET 7/30/13.

Docket Numbers: ER13–1299–000.

Applicants: PacifiCorp.

Description: BPA AC Intertie O&M Agreement Informational Report to be effective N/A.

Filed Date: 7/9/13.

Accession Number: 20130709–5152.

Comments Due: 5 p.m. ET 7/30/13.

Docket Numbers: ER13–1912–000.

Applicants: Guzman Power Markets.

Description: GPM FERC Filing Transmittal Letter to be effective 8/20/2013.

Filed Date: 7/9/13.

Accession Number: 20130709–5118.

Comments Due: 5 p.m. ET 7/30/13.

Docket Numbers: ER13–1913–000.

Applicants: Southern California Edison Company.

Description: Amended LGIA with North Sky River Energy, LLC to be effective 7/10/2013.

Filed Date: 7/9/13.

Accession Number: 20130709–5142.

Comments Due: 5 p.m. ET 7/30/13.

Docket Numbers: ER13–1914–000.

Applicants: Southwest Power Pool, Inc.

Description: Creditable Upgrades Under Attachment Z2 to be effective 9/8/2013.

Filed Date: 7/9/13.

Accession Number: 20130709–5155.

Comments Due: 5 p.m. ET 7/30/13.

Docket Numbers: ER13–1915–000.

Applicants: Public Service Company of Colorado.

Description: 2013_07_09_NSP–SPNR–L-Tran-to Load-NOC–548 to be effective 6/13/2013.

Filed Date: 7/10/13.

Accession Number: 20130710–5000.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1916–000.

Applicants: Arizona Public Service Company.

Description: Amendments to reflect APS Acquisition of portions of Four Corners Units 4&5 to be effective 12/31/9998.

Filed Date: 7/10/13.

Accession Number: 20130710–5001.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1917–000.

Applicants: Arizona Public Service Company.

Description: Amendment of Shiprock Four Corners Project Interconnection AG to be effective 12/31/9998.

Filed Date: 7/10/13.

Accession Number: 20130710–5003.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1918–000.

Applicants: Arizona Public Service Company.

Description: Edison Navajo Transmission Agreement as APS Rate Schedule No. 267 to be effective 12/31/9998.

Filed Date: 7/10/13.

Accession Number: 20130710–5004.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1919–000.

Applicants: PPL Montana, LLC.

Description: PPL Montana, LLC submits Notice of Cancellation of Power Purchase and Sales Agreement with Energy West Resources, Inc.

Filed Date: 7/9/13.

Accession Number: 20130709–5179.

Comments Due: 5 p.m. ET 7/30/13.

Docket Numbers: ER13–1920–000.

Applicants: Wisconsin Electric Power Company.

Description: Wisconsin Electric FERC Electric Tariff Volume No. 9 2013 update to be effective 9/9/2013.

Filed Date: 7/10/13.

Accession Number: 20130710–5030.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1921–000.

Applicants: Wisconsin Electric Power Company.

Description: Wisconsin Electric and WPPI Rate Schedule FERC No. 90 2013 revisions to be effective 9/9/2013.

Filed Date: 7/10/13.

Accession Number: 20130710–5031.

Comments Due: 5 p.m. ET 7/31/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 10, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–17379 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: CP13–513–000.

Applicants: Dominion Transmission, Inc.

Description: Application of Dominion Transmission, Inc. for Abandonment of Rate Schedule X–69.

Filed Date: 7/02/13.

Accession Number: 20130702–5223.

Comments Due: 5 p.m. ET 7/22/13.

Docket Numbers: CP13–517–000.

Applicants: National Fuel Gas Supply Corporation.

Description: Application Pursuant to Section 7(b) for Permission and Approval to Abandon Rate Schedule X–51 submitted by National Fuel Gas Supply Corporation.

Filed Date: 7/08/13.

Accession Number: 20130708–5163.

Comments Due: 5 p.m. ET 7/22/13.

Docket Numbers: CP13–518–000.

Applicants: UGI Penn Natural Gas, Inc.

Description: Application of UGI Penn Natural Gas, Inc for a limited jurisdiction blanket certificate of public convenience and necessity etc.

Filed Date: 7/08/13.

Accession Number: 20130709–0021.

Comments Due: 5 p.m. ET 7/22/13.

Docket Numbers: RP13–1060–000.

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: Maritimes & Northeast Pipeline, L.L.C. submits tariff filing per 154.203: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5043.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1061–000.

Applicants: Ozark Gas Transmission, L.L.C.

Description: Ozark Gas Transmission, L.L.C. submits tariff filing per 154.203: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5044.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1062–000.

Applicants: Saltville Gas Storage Company L.L.C.

Description: Saltville Gas Storage Company L.L.C. submits tariff filing per 154.203: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5048.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1063–000.

Applicants: Southeast Supply Header, LLC.

Description: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5050.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1064–000.

Applicants: Steckman Ridge, LP.

Description: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5052.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1065–000.

Applicants: Texas Eastern Transmission, LP.

Description: ACA Compliance Filing—Docket No. RM12–14–000; Order No. 776 to be effective 10/1/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5053.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1066–000.

Applicants: TWP Pipeline LLC.

Description: TWP Compliance Filing to be effective 5/24/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5084.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1067–000.

Applicants: Cameron Interstate Pipeline, LLC.

Description: Cameron Interstate Pipeline LLC Annual Charge Adjustment Tariff Filing 2013 to be effective 10/1/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5109.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1068–000.

Applicants: LA Storage, LLC.

Description: LA Storage, LLC ACA Tariff Filing 2013 to be effective 10/1/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5118.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1069–000.

Applicants: Rockies Express Pipeline LLC.

Description: Neg Rate 2013–07–11 EOG NC NRA to be effective 7/12/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5128.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1070–000.

Applicants: Tallgrass Interstate Gas Transmission, L.

Description: Neg Rate 07–11–13 MGE to be effective 7/12/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5129.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1071–000.

Applicants: Cimarron River Pipeline, LLC.

Description: Cash Out Refund Report for Cimarron River Pipeline, LLC.

Filed Date: 7/11/13.

Accession Number: 20130711–5141.

Comments Due: 5 p.m. ET 7/23/13.

Docket Numbers: RP13–1072–000.

Applicants: Eastern Shore Natural Gas Company.

Description: General Terms and Conditions Tariff Revisions to be effective 8/11/2013.

Filed Date: 7/11/13.

Accession Number: 20130711–5182.

Comments Due: 5 p.m. ET 7/23/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 15, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–17367 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3178–001.

Applicants: Windstar Energy, LLC.

Description: Windstar Energy, LLC's Supplement to March 25, 2013 Notice of Change in Status and Waiver Request of Certain Reporting Requirements.

Filed Date: 4/8/13.

Accession Number: 20130408–5195.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER11–3417–003; ER10–2895–006; ER11–2292–005; ER11–3942–004; ER11–2293–005; ER10–2917–006; ER11–2294–005; ER12–2447–003; ER10–2918–007; ER12–199–006; ER10–2920–006; ER10–1900–004; ER11–3941–004; ER10–2921–006; ER10–2922–006; ER10–3048–004; ER10–2966–006.

Applicants: Alta Wind VIII, LLC, Bear Swamp Power Company LLC, Brookfield Energy Marketing, Inc., Brookfield Energy Marketing LP, Brookfield Energy Marketing US LLC, Brookfield Renewable Energy Marketing US, Brookfield Smoky Mountain Hydropower LLC, Carr Street Generating Station, L.P., Coram California Development, L.P., Erie Boulevard Hydropower, L.P.,FPL Energy Maine

Hydro LLC, Granite Reliable Power, LLC, Great Lakes Hydro America LLC, Hawks Nest Hydro LLC, Longview Fibre Paper and Packaging, Inc., Rumford Falls Hydro LLC, Brookfield Power Piney & Deep Creek LLC.

Description: Brookfield Companies Supplement to March 25, 2013 Notice of Change in Status.

Filed Date: 4/8/13.

Accession Number: 20130408–5190.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1157–000.

Applicants: Ameren Illinois Company.

Description: Refund Report to be effective N/A.

Filed Date: 7/10/13.

Accession Number: 20130710–5068.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1256–000.

Applicants: The Narragansett Electric Company.

Description: The Narragansett Electric Company submits Refund Report regarding Interconnection Agreement with Pontiac Energy Corp. to be effective N/A.

Filed Date: 7/10/13.

Accession Number: 20130710–5150.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1692–000.

Applicants: Florida Power & Light Company.

Description: Supplement to the FPL and Miami-Dade County Service Agreement No. 124 to be effective N/A.

Filed Date: 7/10/13.

Accession Number: 20130710–5101.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1925–000.

Applicants: Public Service Company of Colorado.

Description: 2013–07–10_333–PSCo TSGT Davis CA to be effective 6/11/2013.

Filed Date: 7/10/13.

Accession Number: 20130710–5097.

Comments Due: 5 p.m. ET 7/31/13.

Docket Numbers: ER13–1931–000.

Applicants: South Jersey Energy ISO3, LLC.

Description: Market Based Rates Tariff to be effective 7/11/2013.

Filed Date: 7/10/13.

Accession Number: 20130710–5131.

Comments Due: 5 p.m. ET 7/31/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 10, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–17381 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[ER13–1922–000; ER13–1929–000; ER13–1932–000; NJ13–11–000]

Duke Energy Florida, Inc.; Florida Power & Light Company; Tampa Electric Company; Orlando Utilities Commission; Notice of Compliance Filings

Take notice that on July 10, 2013, Duke Energy Florida, Inc., Florida Power & Light Company, Tampa Electric Company, and Orlando Utilities Commission, submitted filings to comply with the requirements of Order No. 1000 Interregional Compliance.[1]

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 26, 2013.

Dated: July 12, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–17285 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

[1] *Transmission Planning and Cost Allocation by Transmission Owning and Operating Public Utilities,* 136 FERC ¶ 61,051 (2011), order on reh'g and clarification, 139 FERC ¶ 61,132 (2012) (Order No. 1000–A), order on reh'g and clarification, 141 FERC ¶ 61,044 (2012) (Order No. 1000–B) (Order Nos. 1000, 1000–A, and 1000–B collectively referred to as Order No. 1000, Order, or Final Rule).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM12–3–000]

Revisions to Electric Quarterly Report Filing Process; Notice of Availability of Sandbox Electronic Test Site

Take notice that a Sandbox Electronic Test Site (ETS) and instructions have been posted on the Commission's Web site at *http://www.ferc.gov/docs-filing/eqr.asp.*

Order No. 770 [1] revised the method for making Electric Quarterly Report (EQR) filings. One of the new methods for filing is through a Web interface. The ETS provides an opportunity to use this new method on a trial basis until September 1, 2013.

Staff invites users to email comments and questions concerning the ETS to *eqr@ferc.gov.* Please include ''Sandbox Electronic Test Site'' in the subject line of any such emails.

Further, market participants are encouraged to sign up for the Commission's RSS feed to ensure timely receipt of new and additional information concerning the filing of EQRs. Such information often will not be conveyed through notices such as this one.

[1] *Revisions to Electric Quarterly Report Filing Process,* Order No. 770, 77 FR 71288 (Nov. 30, 2012), FERC Stats. & Regs. ¶ 31,338 (2012).

Dated: July 12, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–17307 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TX13–1–000]

Watson Cogeneration Company; Notice of Filing

Take notice that on July 12, 2013, pursuant to sections 202(b), and 210 of the Federal Power Act, 16 U.S.C. 824a(b), and 824i, Part 36 of the Federal Energy Regulatory Commission's (Commission) Regulations, 18 CFR 36.1, Watson Cogeneration Company filed an application requesting that the Commission direct (1) Southern California Edison (SCE) to continue providing the existing physical interconnection to the Watson facility; (2) direct SCE and California Independent System Operator Corporation to execute the interconnection agreement; and (3) establish the effective date of the interconnection agreement to be contemporaneous with the future and to-be-established effective date of the Watson Transition Power Purchase Agreement.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 12, 2013.

Dated: July 12, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–17283 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD13–5–000]

Flexible and Local Resources Needed for Reliability in the California Wholesale Electric Market; Notice of Staff Technical Conference

This notice establishes the agenda and topics for discussion at the technical conference directed by the Commission in an Order on California Independent System Operator Corporation's (CAISO) proposal to implement an interim flexible capacity and local reliability resource retention mechanism (FLRR).[1] The technical conference will be held on July 31, 2013 from 9:00 a.m. to 4:30 p.m. (Pacific Time) in the Byron Sher Auditorium at the California Environmental Protection Agency Headquarters Building, 1001 I Street, Sacramento, California, 95812. *Please note the changed venue for the conference and the truncation of the conference to a single day.* The technical conference will be led by FERC staff, with presentations from panelists. Commissioners may attend and participate in the conference.

The agenda and questions to be discussed during this conference are attached. The technical conference is intended to facilitate a structured dialogue on the reliability and risk-of-retirement concerns raised in the FLRR proceeding, including, how those concerns relate to the joint CAISO/CPUC Multi-Year Reliability Framework proposal.

The technical conference will not be transcribed. However, there will be a free audiocast of the conference. The audiocast will allow persons to listen to the conference, but not participate. Anyone with Internet access who wants to listen can do so by navigating to the Calendar of Events at *www.ferc.gov* and locating the technical conference in the Calendar. The FERC Web site's link to the technical conference will contain a link to the audiocast. The Capitol Connection provides technical support for the audiocast. If you have questions, visit *www.CapitolConnection.org* or call 703–992–3100.

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–8659 (TTY), or send a fax to 202–208–2106 with the required accommodations.

For more information on this conference, please contact Colleen Farrell at *colleen.farrell@ferc.gov* or (202) 502–6751; or Katheryn Hoke at *katheryn.hoke@ferc.gov* or (202) 502–8404.

Dated: July 11, 2013.

Kimberly D. Bose,

Secretary.

Agenda for the Technical Conference on Flexible and Local Resources Needed for Reliability in the California Wholesale Electric Market July 31, 2013

The technical conference is intended to facilitate a structured dialogue on the reliability and risk-of-retirement concerns raised in the FLRR proceeding, including discussion of the possible development of a durable, market-based mechanism to provide incentives to insure reliability needs are met.

The CAISO and CPUC staff recently announced a joint Multi-Year Reliability Framework proposal (joint proposal) for revising the CPUC's resource adequacy program and CAISO's capacity procurement mechanism tariff provisions, that is related to this subject.[2] Thus, this technical conference will also examine whether and how the joint proposal addresses the reliability needs raised in the FLRR proceeding.

Following a presentation by CAISO and CPUC staff, the conference will be divided into two panels. The first panel will examine the reliability issues raised in the FLRR proceeding and will also consider implications of the joint proposal for a Multi-Year Reliability Framework. The second panel will review possible solutions to the

[1] *Cal. Indep. Sys. Operator Corp.,* 142 FERC ¶ 61,248 (2013).

[2] See *http://www.caiso.com/Documents/NewStakeholderInitiativeMulti-YearReliabilityFramework_ISO-CPUCJointWorkshopJul17_2013.htm.*

concerns that were raised in the FLRR proceeding as they pertain to flexible and local resources and whether the joint Multi-Year Reliability Framework offers a potential solution. This notice provides focus areas around which speakers should concentrate their comments. Each panelist should limit his presentation to 8 minutes. The panels will be followed by questions from Commissioners and CPUC and FERC staff, with an opportunity for audience members to participate.

Technical Conference Schedule

9:00 a.m.–9:15 a.m. Opening Remarks
Greeting and Opening Remarks
9:15 a.m.–10:15 a.m. Joint CAISO/CPUC presentation
The presentation is expected to last 30 minutes and will be followed by Q&A
10:15 a.m.–11:15 a.m. Panel discussion on the risk-of-retirement problem and its contribution to reliability
Each panelist should limit his presentation to 8 minutes. The panel will be followed by questions from Commissioners and CPUC and FERC staff.
Panel one will be comprised of:
—Todd Strauss representing Pacific Gas & Electric Company;
—Pedro Pizarro representing Edison Mission Energy;
—Gary Ackerman representing Western Power Trading Forum;
—Kevin Woodruff representing The Utility Reform Network;
—Carl Zichella representing the National Resources Defense Council; and
—Kevin Carden representing Astrape Consulting.

Questions for Panel One: With respect to the reliability concerns raised in the FLRR proceeding, staff requests that panelists include in the presentations discussion of some of the questions below.

➢ In the FLRR proceeding, CAISO identified reliability concerns resulting from the retirement of resources needed for reliable operations. Are the resources necessary to ensure reliability over a forward looking period entering the market? If not, why not? For instance, how do the current CAISO market and bilateral capacity market structures influence resources' decisions to enter the market or retire? Are additional compensation structures required to ensure that resources needed for reliability are available over a forward period? What factors, besides compensation, may be influencing retirement and entry decisions in CAISO?

➢ What sort of operational and reliability conditions, including those that could lead to NERC/WECC reliability standard violations, will CAISO face based on assessments of a forward-looking period including projections of resources that enter the market, resources that will retire, load projections, demand response, etc.?

➢ What are the appropriate planning and operating assumptions to use in determining the forward-looking system needs for flexible resources that are needed to ensure overall system reliability? How much flexible capacity will be needed to ensure that the resource mix in CAISO is able to ensure reliable operations?

➢ How would a resource qualify as a flexible resource and what is an appropriate range of performance characteristics? Should there be an ongoing certification process for flexible resources? What other resource characteristics are important to ensure reliability in CAISO?

➢ Are there barriers to extracting flexible capability out of the existing fleet of resources?

➢ What are the causes of a resource being at risk-of-retirement? How is the market informed that a resource is at risk-of-retirement?

➢ How should local capacity needs and potential reliability issues associated with deliverability be addressed? Does the need to retain resources for local reliability require a mechanism that is unique from a market-based option for flexible capacity retention?

➢ What are the appropriate procurement targets for system, flexible and local capacity in the two- and three-year forward periods? How should the technical assessment be updated from year-to-year to account for changing market conditions, changing system configuration and changes in demand over the forward period?

➢ Would the provision in the joint proposal to limit load serving entities' participation in the residual capacity auction impact the effectiveness of forward procurement for reliability purposes? Why or why not?

11:15 a.m.–12:15 p.m. Open Discussion Time
12:15 p.m.–1:15 p.m. Lunch
1:15 p.m.–2:30 p.m. Panel discussion exploring whether a multi-year resource adequacy framework with a CAISO backstop is a solution to risk of retirement
Each panelist should limit his presentation to 8 minutes. The panels will be followed by questions from Commissioners, CPUC and FERC staff.
Panel two will be comprised of:
- Marc Ulrich representing Southern California Edison Company;
—Mark Smith or Matthew Barmack representing Calpine;
—Tony Braun representing California Municipal Utilities Association;
—Joe Como representing the CPUC Division of Ratepayer Advocates;
—Steven Kelly representing the Independent Energy Producers Association;
—Mike Evans representing Shell Energy; and
—Michael Milligan representing National Renewable Energy Laboratory.

Questions for Panel Two: With respect to the concerns raised in the FLRR proceeding regarding a market-based means of addressing forward-looking system, local and flexible needs, including when resources are at risk of retirement but needed in future years for reliability, staff requests that panelists include in the presentations discussion of some of the questions below.

➢ What are the preferred market-based solutions that could be used to address the forward flexible and local reliability concerns raised in the FLRR proceeding?

➢ How would a forward procurement requirement, along with specific procurement targets for flexible and local resources, affect bilateral contract prices?

➢ Would the joint proposal's combination of multi-year ahead flexible capacity obligations procured through bi-lateral contracts, or via CAISO backstop procurement, provide sufficient revenues to resources?

➢ Will the joint proposal's limited forward procurement of flexible and local capacity pursuant to a three-year forward resource adequacy obligation backed by a market-based CAISO backstop procurement mechanism provide sufficient procurement tools and sufficient additional revenue to mitigate the risk of retirement and retain needed flexible and local resources?

➢ Will the joint proposal's voluntary backstop capacity market, along with market power mitigation measures, provide sufficient replacement for the capacity procurement mechanism when it sunsets in 2015? If a mechanism like the joint proposal were implemented, would CAISO still need an interim risk-of-retirement backstop mechanism and what would any such backstop mechanism look like?

➢ Is there a mechanism needed prior to the potential implementation of the joint proposal? For instance, is an interim mechanism necessary to procure resources at risk of retirement that are

needed for flexibility? If so, what kind of mechanism?

➢ With respect to the goal of retaining flexible and local resources for reliability purposes that may be at risk of retirement, what alternatives to the joint proposal should be considered?

2:30 p.m.–2:45 p.m. Break

2:45 p.m.–4:15 p.m. Open Discussion Time

This time will be reserved for follow-up discussion on any issues raised during the panel discussions, or to address miscellaneous concerns related to the Multi-Year Reliability Framework, including questions or comments from members of the audience.

4:15 p.m.–4:30 p.m. Closing Remarks

[FR Doc. 2013–17290 Filed 7–18–13; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9010–2]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 07/08/2013 Through 07/12/2013 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20130208, Draft EIS, USFS, CO, Gore Creek Restoration, Comment Period Ends: 09/03/2013, Contact: Jack Lewis 970–638–4176.

EIS No. 20130209, Draft EIS, BLM, AZ, Sonoran Valley Parkway Project, Comment Period Ends: 09/03/2013, Contact: Kathleen Depukat 623–580–5681.

EIS No. 20130210, Draft EIS, DOE, CA, Hydrogen Energy California Integrated Gasification Combined Cycle Project, Comment Period Ends: 09/03/2013, Contact: Fred Pozzuto 304–285–5219.

EIS No. 20130211, Final EIS, USN, MD, Medical Facilities Development and University Expansion at Naval Support Activity Bethesda, Review Period Ends: 08/19/2013, Contact: Joseph Macri 301–295–1803.

EIS No. 20130212, Final EIS, BLM, AZ, APS Sun Valley to Morgan 500/230kV Transmission Line Project, Proposed Resource Management Plan Amendment, Review Period Ends: 08/19/2013, Contact: Joe Incardine 801–560–7135.

Amended Notices

EIS No. 20130122, Final EIS, MARAD, AL, ADOPTION—Garrows Bend Intermodal Rail, Portion of the Choctaw Point Terminal Project, Review Period Ends: 08/19/2013, Contact: Kris Gilson 202–492–0479. The U.S. Department of Transportation's Maritime Administration has adopted the U.S. Army Corps of Engineers FEIS #20040381, filed 08/10/2004. The Maritime Administration was not a cooperating agency, therefore recirculation is necessary under Section 1506.3(b) of the CEQ Regulation.

Revision to FR Notice Published 05/03/2013: CEQ Wait Period Ending 06/03/2013 has been reestablished to 08/19/2013.

EIS No. 20130161, Draft EIS, USFS, MT, East Reservoir Project, Comment Period Ends: 08/15/2013, Contact: Denise Beck 406–293–7773 Ext.7504

Revision to FR Notice Published 07/26/2013; Extending Comment Period from 07/29/2013 to 08/15/2013.

EIS No. 20130200, Final EIS, FTA, CA, Van Ness Bus Rapid Transit Project, Review Period Ends: 08/12/2013, Contact: Alex Smith 415–744–3133.

Revision to FR Notice Published 07/12/2013; Correction to Agency Contact Name should be Alex Smith.

Dated: July 16, 2013.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2013–17424 Filed 7–18–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2013–0484; FRL–9835–6]

Proposed Settlement Agreement, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement agreement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''CAA'' or the ''Act''), notice is hereby given of a proposed settlement agreement to address a lawsuit filed by Communities for a Better Environment, California Communities Against Toxics, Desert Citizens Against Pollution, Natural Resources Defense Council, and Physicians for Social Responsibility–Los Angeles (collectively ''Petitioners'') in the United States Court of Appeals for the Ninth Circuit: *Communities for a Better Environment, et al.* v. *EPA,* No. 12–71340, (9th Cir.). On April 30, 2012, Petitioner filed a petition for review challenging EPA's final action to approve the state implementation plan (SIP) revisions submitted by California to provide for attainment of the 1997 8-hour ozone national ambient air quality standard in the Los Angeles-South Coast area (''South Coast''). The proposed settlement agreement establishes a deadline for EPA to take action on subsequently submitted SIP revisions for the South Coast.

DATES: Written comments on the proposed settlement agreement must be received by *August 19, 2013.*

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2013–0484, online at *www.regulations.gov* (EPA's preferred method); by email to *oei.docket@epa.gov;* by mail to EPA Docket Center, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC, between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Word or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

FOR FURTHER INFORMATION CONTACT: Jan Tierney, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: (202) 564–5598; fax number (202) 564–5603; email address: *tierney.jan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Settlement Agreement

The proposed settlement agreement would resolve a lawsuit seeking to overturn EPA's final action to approve SIP revisions submitted by California to provide for attainment of the 1997 8-hour ozone national ambient air quality standard in the South Coast. 77 FR 12674 (March 1, 2012). The proposed settlement agreement requires that no later than August 13, 2014, EPA shall sign a notice or notices of the Agency's final action or actions under Section

110(k) of the CAA on certain SIP revisions submitted by California on February 13, 2013, including a new attainment demonstration plan for the 1-hour ozone standard in the South Coast and new demonstrations intended to comply with Section 182(d)(1)(A) of the CAA, 42 U.S.C. 7511a(d)(1)(A), for the 1-hour ozone and 1997 8-hour ozone standards. Thereafter, EPA shall send the notice(s) to the Office of the Federal Register for review and publication. After EPA fulfills its obligations under the agreement, the Petitioners shall dismiss this matter, but Petitioners reserve any rights they may have to challenge EPA final action or actions on the above described SIP revisions.[1] If EPA does not take action by the deadline, then Petitioners' sole remedy under the proposed agreement shall be the right to request that the Ninth Circuit lift the stay of proceedings and establish a schedule for briefing and oral argument.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed settlement agreement from persons who were not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed settlement agreement if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this settlement agreement should be withdrawn, the terms of the agreement will be affirmed.

II. Additional Information About Commenting on the Proposed Settlement Agreement

A. How can I get a copy of the settlement agreement?

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2013–0484) contains a copy of the proposed settlement agreement. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *www.regulations.gov.* You may use *www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search''.

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an ''anonymous access'' system. If you send an email comment directly to the Docket without going through *www.regulations.gov,* your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: July 11, 2013.

Lorie J. Schmidt,

Associate General Counsel.

[FR Doc. 2013–17436 Filed 7–18–13; 8:45 am]

BILLING CODE 6560–50–P

[1] Four of the five Petitioners have also noticed an appeal from dismissal of *Physicians for Social Responsibility—Los Angeles* v. *EPA,* No. 2:11–cv–05885–GW–SS, in the United States District Court for the Central District of California, currently docketed in the Ninth Circuit as Case No. 12–56175. Under the proposed settlement agreement, the four petitioners who are appellants in that case shall dismiss *Physicians for Social Responsibility—Los Angeles* v. *EPA,* No. 12–56175, upon receipt of written notice from EPA that the proposed settlement agreement is final.

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday, July 23, 2013 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This Meeting Will Be Closed to the Public.

ITEMS TO BE DISCUSSED: Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Matters that relate solely to the Commission's internal personnel decisions, or internal rules and practices.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

* * * * *

Person To Contact For Information: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Signed:

Shawn Woodhead Werth,

Secretary and Clerk of the Commission.

[FR Doc. 2013–17417 Filed 7–17–13; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

The Commission gives notice that the following applicants have filed an application for an Ocean Transportation Intermediary (OTI) license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF) pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101). Notice is also given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a licensee.

Interested persons may contact the Office of Ocean Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at *OTI@fmc.gov.*

Aduanir Cargo & Courier Corp. (NVO & OFF), 5900 NW 79th Avenue, Doral, FL 33178, Officers: Anamar Del Castillo, Vice President (QI), Jesus Cachazo, President, Application Type: New NVO & OFF License.

AGRI Ocean Service, Inc. (NVO & OFF), 1952 McDowell Road, Suite 303, Naperville, IL 60563, Officers: Michael A. Mays, Vice President (QI), Hsiao C. Shyu, Shareholder, Application Type: New NVO & OFF License.

Allen Lund Company, LLC (NVO & OFF), 4529 Angeles Crest Highway, Suite 300, La Canada, CA 91011, Officers: Tanya J. Poston, Vice President (QI), Allen Lund, President, Application Type: QI Change.

Allround Forwarding Holding, Inc. (NVO & OFF), 134 West 26th Street, New York, NY 10001, Officers: Hatto H. Dachgruber, President (QI), John Wellock, Vice President, Application Type: Name Change to Allround Forwarding Co., Inc.

Alsea Global Logistics, LLC dba Alsea Global Logistics (NVO & OFF), 4836 SE Powell Blvd., Portland, OR 92706, Officers: Sandra K. Thoroughman, Operations Director (QI), Keith E. Ashcraft, Chief Executive Officer, Application Type: New NVO & OFF License.

Armada Services, LLC. (NVO & OFF), 519 S. Ellwood Avenue, 2nd Floor, Baltimore, MD 21224, Officer: Katrina N. Dill, Managing Member (QI), Application Type: New NVO & OFF License.

Atlant Consulting Inc. dba Avro Logistics (NVO & OFF), 3626 Geary Blvd., Suite 206, San Francisco, CA 94118, Officers: Tatyana Lizyura, Corporate Secretary, Konstantin Pletney-Veller, CEO, Application Type: New NVO & OFF License.

BeavEx Incorporated (NVO), 329 Air Freight Blvd., Nashville, TN 37217, Officers: David W. Hofer Jr., Vice President (QI), Mark Tuchmann, President, Application Type: New NVO License.

BFB North America Inc. dba Miami Ocean Carriers (NVO), 18503 Pines Blvd., Suite 206, Pembroke Pines, FL 33029, Officer: Cenovia Huanaquiri, President (QI), Application Type: New NVO License.

Blue Cargo Group, LLC (NVO & OFF), 10301 NW 108th Avenue, Suite 6, Miami, FL 33178, Officers: Paul Selvage, Member (QI), Steven Periman, Member/Manager, Application Type: Add Trade Name Blu Logistics and QI Change.

CCP International (Shipping) Inc. (OFF), 1717 Hyde Park Avenue, Hyde Park, MA 02136, Officers: Adeyemi J. Adegboyega, President (QI), Ademipo C. Adegboyega, Treasurer, Application Type: New OFF License.

Continental Connection LLC (NVO & OFF), 150 Sanctuary Ct., Columbus, OH 43235, Officer: David E. Day, Managing Member (QI), Application Type: New NVO & OFF License.

Eurybia Logistics, Inc. (NVO), 2560 Corporate Place, Suite D107, Monterey Park, CA 91754, Officer: Zhang Yi, President (QI), Application Type: New NVO License.

Global Relocation Inc (NVO), 250 Pehle Avenue, Suite #200, Saddle Brook, NJ 07663, Officers: Farah Alhomsi, Vice President (QI), Rami Zubidat, President, Application Type: New NVO License.

JAG Cargo Inc. (OFF), 7520 SW 107th Avenue, Apt. 107, Miami, FL 33173, Officers: Javier A. Garcia, President (QI), Pedro O. Garcia, Treasurer, Application Type: New OFF License.

Laser International Transportation Incorporated (NVO), 1940 Internationale Parkway, Suite 300, Woodridge, IL 60517, Officer: Joseph P. Specht Jr., President (QI), Application Type: New NVO License.

LH Global Inc. (NVO), 2737 Brook Avenue, Oceanside, NY 11572, Officers: Guilan He, Vice President (QI), Xiao Ying Liu, President, Application Type: New NVO License.

Miragrown Logistics Corporation (NVO), 2370 West Carson Street, Suite 130, Torrance, CA 90501, Officers: Katie Lee, Secretary (QI), Zhimin Wei, President, Application Type: New NVO License.

Morgan Systems, Inc. (NVO & OFF), 1500 Cedar Grove Road, Conley, GA 30288, Officers: David C. McCormack, Vice President (QI), David G. Morgan, Owner, Application Type: New NVO & OFF License.

Popi Trading, Inc. dba Liner American Services N.A. (OFF), 225 Broadway, Suite 2701, New York, NY 10007, Officers: Pablo Silva, President (QI), Ana Belen Perez, Secretary, Application Type: New OFF License.

Rodi International Corp. (NVO & OFF), 2801 NW 74th Avenue, Suite 200, Miami, FL 33122, Officers: Dorian F. Rodriguez, President (QI), Doris Del Castillo, Secretary, Application Type: New NVO & OFF License.

Safari Cargo, LLC (NVO & OFF), 7007 Gulfway Freeway, Suite 107, Houston, TX 77087, Officer: Maged L. Ghazi, Member (QI), Application Type: New NVO & OFF License.

Stoneland Global Logistics, Inc. (NVO & OFF), 19051 Kenswick Drive, Suite 170, Humble, TX 77338, Officers: Jorge A. Moreno, Vice President (QI), Robert Shannon, President, Application Type: New NVO & OFF License.

Straight Point Line Inc. (NVO & OFF), 72 Sharp Street, Suite C11, Hingham, MA 02043, Officer: Paul F. Kalita, President (QI), Application Type: Name Change to Outsource, Inc.

Topp Cargo & Logistics, LLC (NVO & OFF), 8000 NW 29th Street, Miami, FL 33122, Officers: Adrian Martinez, Operations Manager (QI), Jose G. Suarez, Sales Manager, Application Type: QI Change.

UBA Express Cargo, Corp. (NVO), 10350 West Flagler Street, Miami, FL 33174, Officer: Martha E. Rivas, President (QI), Application Type: New NVO License.

Ucans Global, Inc (NVO), 1420 Francisco Street, Torrance, CA 90501, Officer: Jaden O. Lee, President (QI), Application Type: New NVO License.

By the Commission.

Dated: July 15, 2013.

Karen V. Gregory,

Secretary.

[FR Doc. 2013–17308 Filed 7–18–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations and Terminations

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been revoked or terminated for the reason shown pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 3388NF.
Name: OCI Forwarding Services, Inc. dba Metro Line.
Address: 1225 Greenbriar Drive, Suite E, Addison, IL 60101.
Date Revoked: May 30, 2013.
Reason: Failed to maintain a valid bond.

License No.: 3714F.
Name: A & E International, Inc.
Address: 16449 1–45 Feeder South. Centerville, TX 75833.
Date Revoked: June 1, 2013.
Reason: Voluntary Surrender of License.

License No.: 4097F.
Name: Ashby, Wendy Lyn dba Cargocare.
Address: 107 Woodcrest Drive, Chehalis, WA 98532.
Date Revoked: June 6, 2013.
Reason: Failed to maintain a valid bond.

License No.: 4313F.
Name: Lopez, Miguel Angel dba Marine Air Land International Services.
Address: 3478 Investment Blvd., Hayward, CA 94545.
Date Revoked: June 8, 2013.
Reason: Failed to maintain a valid bond.

License No.: 17123N.
Name: Express Freight International, Inc.
Address: 2027 Williams Street, San Leandro, CA 94577.
Date Revoked: May 24, 2013.
Reason: Failed to maintain a valid bond.

License No.: 017292N.
Name: Pudong Trans USA, Inc.
Address: 9660 Flair Drive, Suite 328, El Monte, CA 91731.
Date Revoked: May 26, 2013.
Reason: Failed to maintain a valid bond.

License No.: 019906F.
Name: Atlantic Air Express, LLC.
Address: 1893 Country Route 1, Westtown, NY 10998.
Date Revoked: June 18, 2013.
Reason: Voluntary Surrender of License.

License No.: 021156F.
Name: Aprile USA, Inc. dba Allied Seafreight Line.
Address: 1370 Broadway, Suite 1400, New York, NY 10018.
Date Revoked: June 1, 2013.
Reason: Failed to maintain a valid bond.

License No.: 021995F.
Name: Deakins Trans-Global Logistics, LLC.
Address: 6817 South Point Parkway, Suite 101, Jacksonville, FL 32216.
Date Revoked: June 8, 2013.
Reason: Failed to maintain a valid bond.

License No.: 022605N.
Name: AK Solutions Inc.
Address: 10034 Halston Drive, Sugarland, TX 77498.
Date Revoked: May 27, 2013.
Reason: Failed to maintain a valid bond.

License No.: 022714N.
Name: Seapassion Logistics Inc.
Address: 20819 Currier Road, Unit 400, City of Industry, CA 91789.
Date Revoked: June 3, 2013.
Reason: Failed to maintain a valid bond.

License No.: 023800F.
Name: Joseph P. Solomon dba Equitorial Import-Export.
Address: 20526 76th Avenue West, Suite A, Edmonds, WA 98026.
Date Revoked: June 11, 2013.
Reason: Failed to maintain a valid bond.

License No.: 023846NF.
Name: International Cargo Shipping LLC.
Address: 11354 Burbank Blvd., Suite C, North Hollywood, CA 91601.
Date Revoked: June 6, 2013.
Reason: Failed to maintain a valid bond.

James A. Nussbaumer,
Deputy Director, Bureau of Certification and Licensing.

[FR Doc. 2013–17309 Filed 7–18–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 5, 2013.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Veranda L. Dickens,* Chicago, Illinois; to acquire voting shares of Seaway Bancshares, Inc., and thereby indirectly acquire voting shares of Seaway Bank and Trust Company, both in Chicago, Illinois.

B. Federal Reserve Bank of St. Louis (Yvonne Sparks, Community Development Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. *Richard A. Torti, Sr., as executor of the estate of Layton P. Stuart,* both of Little Rock, Arkansas; to retain voting shares of OneFinancial Corporation, and thereby indirectly retain voting shares of One Bank & Trust, National Association, both in Little Rock, Arkansas.

Board of Governors of the Federal Reserve System, July 16, 2013.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

[FR Doc. 2013–17357 Filed 7–18–13; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0074: Sequence 44]

Federal Acquisition Regulation; Submission for OMB Review; Contract Funding—Limitation of Costs/Funds

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension of an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning limitation of costs/funds. A notice was

published in the **Federal Register** at 77 FR 75163, on December 19, 2012. Two comments were received.

DATES: Submit comments on or before August 19, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0074, Contract Funding—Limitation of Costs/Funds by any of the following methods:

- *Regulations.gov: http://www.regulations.gov*.

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0074, Contract Funding—Limitation of Costs/Funds''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0074, Contract Funding—Limitation of Costs/Funds'' on your attached document.

- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., 2nd Notice, Washington, DC 20405–0001. ATTN: Hada Flowers/IC 9000–0074, Contract Funding—Limitation of Costs/Funds.

Instructions: Please submit comments only and cite Information Collection 9000–0074, Contract Funding—Limitation of Costs/Funds, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Edward N. Chambers, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA (202) 501–3221 or email *Edward.chambers@gsa.gov*.

SUPPLEMENTARY INFORMATION:

A. Purpose

Firms performing under Federal cost-reimbursement contracts are required to notify the contracting officer in writing whenever they have reason to believe—

(1) The costs the contractors expect to incur under the contracts in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost of the contracts; or

(2) The total cost for the performance of the contracts will be greater or substantially less than estimated.

As a part of the notification, the contractors must provide a revised estimate of total cost.

B. Discussion and Analysis

One respondent submitted public comments on the extension of the previously approved information collection. The analysis of these public comments is summarized as follows:

Comment: The respondent commented that the extension of the information collection would violate the fundamental purposes of the Paperwork Reduction Act because of the burden it puts on the entity submitting the information and the agency collecting the information.

Response: In accordance with the Paperwork Reduction Act (PRA), agencies can request OMB approval of an existing information collection. The PRA requires that agencies use the **Federal Register** notice and comment process, to extend OMB's approval, at least every three years. This extension, to a previously approved information collection, pertains to FAR clauses 52.232–20 and 52.232–22. These clauses require contractors performing under Federal cost-reimbursement contracts to notify the contracting officer in writing whenever they have reason to believe—

(1) The costs the contractors expect to incur under the contracts in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost of the contracts; or

(2) The total cost for the performance of the contracts will be greater or substantially less than estimated. As a part of the notification, the contractors must provide a revised estimate of total cost.

These notifications assist the Government in its effort to provide timely funding of cost reimbursement contracts. The lack of such notifications increases the risk that funding may lapse, resulting in contract work stoppages. This clause has existed substantially the same since the inception of the FAR.

Comment: The respondent commented that the agency did not accurately estimate the public burden, challenging that the agency's methodology for calculating it is insufficient and inadequate and does not reflect the total burden. First, the respondent questioned the basis for the estimated number of respondents of 3,598, stating that it appears to be understated. The respondent also questioned the basis for the estimate of 15.96999 responses per respondent, stating that the five decimal places imply a precise calculation underlying the estimate. Finally, the respondent stated that the average burden estimate of 0.5 hours per response is unrealistically low and unsubstantiated. For this reason, the respondent contends that the agency should reassess the estimated total burden hours and revise the estimate upwards to be more accurate, as was done in FAR Case 2007–006. The same respondent also provided that the burden of compliance with the information collection requirement outweighs any potential utility of the extension.

Response: Serious consideration is given, during the open comment period, to all comments received and adjustments are made to the paperwork burden estimate based on reasonable considerations provided by the public. This is evidenced, as the respondent notes, in FAR Case 2007–006 where an adjustment was made from the total preparation hours from three to 60. This change was made considering particularly the hours that would be required for review within the company, prior to release to the Government.

The burden is prepared taking into consideration the necessary criteria in OMB guidance for estimating the paperwork burden put on the entity submitting the information. For example, consideration is given to an entity reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. The estimated burden hours for a collection are based on an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. Also, the estimated burden hours should only include projected hours for those actions which a company would not undertake in the normal course of business. Careful consideration went into assessing the estimated burden hours for this collection, and although the respondent provided estimates of responses and burden hours, the estimates cannot be confirmed with any degree of certainty to totally rely on the information. However, it is determined that an upward adjustment is warranted at this time based upon consideration of the information provided in the public comment. The information collection requirement has been revised to reflect an overall increase in the total public burden hours.

The estimates of the number of respondents and the number of responses per respondent are based on data from the Federal Procurement Data System—Next Generation (FPDS–NG) for Fiscal Year (FY) 2011. For FY 2011 there were 3,598 unique vendors with 57,460 funding only actions under cost reimbursement contracts. These funding

actions are usually the result of the notification required by this information requirement. The number of responses per respondent (15.96999) was derived by dividing the number of actions by the number of unique vendors. The preciseness of the number of responses demonstrates the level of review and the serious consideration given to the data gathered for this information collection. However, in response to the public comment received, the number of responses per respondent has been rounded up to 16.

With regard to the estimate of 0.5 hours per response, we believe that the notification typically involves an observation of the contractors accounting and financial reporting system that available funds will fall below the 75 percent threshold within the next 60 days, followed by a very brief letter to the contracting officer referencing the applicable contract clause at FAR 52.232–20 or FAR 52.232–22. The contractor's responsibility to foresee the availability of funds and probable cost overruns carries with it a duty to maintain an accounting and financial reporting system capable of securing timely knowledge of all probable costs before they are incurred. This information collection does not require contractors to create or maintain any record or system that the contractor does not maintain in its ordinary course of business. Therefore, the estimated burden hour per response of 30 minutes for this collection of information is valid. However, the rounding of the annual number of responses per respondent from 15.96999 to 16, based upon consideration of the information provided by the respondent, resulted in a revision to the information collection requirement to reflect an overall increase in the total public burden hours.

C. Annual Reporting Burden

Respondents: 3,598.

Responses Per Respondent: 16.

Annual Responses: 57,568.

Hours Per Response: .500.

Total Burden Hours: 28,784.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., 2nd Floor, Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0074, Contract Funding—Limitation of Costs/Funds, in all correspondence.

Dated: July 15, 2013.

Karlos Morgan,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–17389 Filed 7–18–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 51; OMB Control No. 9000–0108]

Federal Acquisition Regulation; Submission for OMB Review; Bankruptcy (FAR Subpart 42.9; 52.242–13)

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding the extension of a previously existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Bankruptcy. A notice was published in the **Federal Register** at 77 FR 73660, December 11, 2012. No comments were received.

DATES: Submit comments on or before August 19, 2013.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: General Services Administration, FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503. Please cite OMB Control No. 9000–0108, Bankruptcy, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Curtis E. Glover, Sr., Procurement Analyst, Contract Policy Division, GSA, (202) 501–1448 or email *curtis.glover@gsa.gov.*

A. Purpose

Under statute, contractors may enter into bankruptcy which may have a significant impact on the contractor's ability to perform its Government contract. The Government often does not receive adequate and timely notice of this event. The clause at 52.242–13 requires contractors to notify the contracting officer within 5 days after the contractor enters into bankruptcy.

B. Annual Reporting Burden

Respondents: 790.

Responses per Respondent: 1.

Annual Responses: 790.

Hours per Response: 1.25.

Total Burden Hours: 988.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., 2nd Floor, Washington, DC 20405–0001, telephone (202) 501–4755. Please cite OMB Control No. 9000–0108, Bankruptcy, in all correspondence.

Dated: July 15, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Governmentwide Policy, Office of Acquisition Policy.

[FR Doc. 2013–17390 Filed 7–18–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Docket No. ATSDR–2013–0002]

Proposed Substances To Be Evaluated for Set 27 Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Request for comments on the proposed substances to be evaluated for Set 27 toxicological profiles.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR) within the Department of Health and Human Services (HHS) is initiating the development of its 27th set of toxicological profiles (CERCLA Set 27). This notice announces the list of proposed substances that will be evaluated for Comprehensive Environmental Response Compensation and Liability Act(CERCLA) Set 27 toxicological profile development. ATSDR's Division of Toxicology and Human Health Sciences is soliciting public nominations from the list of proposed substances to be evaluated for toxicological profile development. ATSDR also will consider the nomination of any additional, non-CERCLA substances that may have

public health implications, on the basis of ATSDR's authority to prepare toxicological profiles for substances not found at sites on the National Priorities List. The agency will do so in order to ''...establish and maintain inventory of literature, research, and studies on the health effects of toxic substances'' under CERCLA Section 104(i)(1)(B), to respond to requests for consultation under section 104(i)(4), and to support the site-specific response actions conducted by ATSDR, as otherwise necessary.

DATES: Nominations from the Substance Priority List and/or additional substances must be submitted on or before August 19, 2013.

ADDRESSES: You may submit nominations, identified by Docket No. ATSDR–2013–0002, by any of the following methods:

**Internet:* Access the Federal eRulemaking portal at *http://www.regulations.gov.* Follow the instructions for submitting comments.

**Mail:* Division of Toxicology and Human Health Sciences, 1600 Clifton Rd. NE., MS F–57, Atlanta, Ga., 30333 *Instructions:* All submissions must include the agency name and docket number for this notice. All relevant comments will be posted without change. This means that no confidential business information or other confidential information should be submitted in response to this notice. Refer to the section *Submission of Nominations* (below) for the specific information required.

FOR FURTHER INFORMATION CONTACT: For further information, please contact Commander Jessilynn B. Taylor, Division of Toxicology and Human Health Sciences, 1600 Clifton Rd. NE., MS F–57, Atlanta, Ga., 30333, Email: *tpcandidatecomments@cdc.gov;* phone: 1–800–232–4636.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9601 *et seq.*] amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) [42 U.S.C. 9601 *et seq.*] by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) with regard to hazardous substances most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the ATSDR Administrator to prepare toxicological profiles for each substance included on the Priority List of Hazardous Substances. This list identifies 275 hazardous substances that ATSDR and EPA have determined pose the most significant current potential threat to human health. The availability of the revised list of the 275 priority substances was announced in the **Federal Register** on November 3, 2011 (76 FR 68193). For prior versions of the list of substances, see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17,1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744); November 17, 1997 (62 FR 61332); October 21, 1999 (64 FR 56792); October 25, 2001 (66 FR 54014), November 7, 2003 (68 FR 63098); December 7, 2005 (70 FR 70284); and March 6, 2008 (73 FR 12178).

Substances To Be Evaluated for Set 27 Toxicological Profiles

Each year, ATSDR develops a list of substances to be considered for toxicological profile development. The Set 27 nomination process includes consideration of all substances on ATSDR's Priority List of Hazardous Substances, also known as the Substance Priority List (SPL), as well as other substances nominated by the public. The 275 substances on the SPL will be considered for Set 27 Toxicological Profile development. This list may be found at the following Web site: *www.atsdr.cdc.gov/SPL* and in the docket at *www.regulations.gov*

Submission of Nominations for the Evaluation of Set 27 Proposed Substances: Today's notice invites voluntary public nominations for substances included on the SPL and for substances not listed on the SPL. All nominations should include the full name of the nominator, affiliation, email address. When nominating a non-SPL substance, please include the rationale for the nomination. Please note email addresses will not be posted on *www.regulations.gov.*

ATSDR will evaluate all data and information associated with nominated substances and will determine the final list of substances to be chosen for toxicological profile development. Substances will be chosen according to ATSDR's specific guidelines for selection. These guidelines can be found in the *Selection Criteria* announced in the **Federal Register** on May 7, 1993 (58FR27286–27287). A hard copy of the Selection Criteria is available upon request or may be accessed at: *http://www.atsdr.cdc.gov/toxprofiles/guidance/criteria_for_selectingtpsupport.pdf.*

Please ensure that your comments are submitted within the specified nomination period. Nominations received after the closing date will be marked as late and may be considered only if time and resources permit.

Dated: July 11, 2013.

Sascha Chaney,

Acting Director, Office of Policy, Planning and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

[FR Doc. 2013–17355 Filed 7–18–13; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13–13ZZ]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 and send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Evaluation of the SAMHSA PDMP Electronic Health Record (EHR) Integration and Interoperability Expansion Program—New—National Center for Injury Prevention and Control (NCIPC), Center for Disease Control and Prevention (CDC).

Background and Brief Description

In 2009, drug overdose deaths became the leading cause of injury death in the United States (U.S.), exceeding motor vehicle traffic crash deaths for the first time, a trend that continued in 2010. Prescription drugs, particularly opioid pain relievers, have been identified as the main driver of this increase. The number of overdose deaths per year involving opioid pain relievers increased more than four-fold from 1999 to 2010 (from 4,030 to 16,651), outnumbering overdose deaths involving all illicit drugs combined. Morbidity associated with opioid pain reliever abuse increased in parallel. The rate of emergency department visits associated with the misuse or abuse use of opioid pain relievers increased 153% from 2004 to 2011, while rates for illicit drugs remained largely stable.

Concurrent to this rise in overdose death rates, the sales of opioid pain relievers have increased four-fold since 1999. According to the National Survey of Drug Use and Health, the primary source of prescription drugs for non-medical use is from prescribed and dispensed prescriptions; more than 70% of those who reported non-medical use of pain relievers said they obtained the pain reliever they most recently used from a friend or relative. Moreover, multiple studies have found an association between increased opioid prescribing—in the amount prescribed per prescription, the total days' supply, and the number of prescriptions per patient—and increased morbidity and mortality in the U.S. over the last 10 to 15 years.

Prescription Drug Monitoring Programs (PDMPs) are now recognized as a key tool in federal, state, and local efforts to address prescription drug abuse and misuse. PDMPs are state databases to which pharmacies and other dispensers report dispensed outpatient controlled substance prescription information. Forty-nine states have passed legislation authorizing a PDMP, and 45 states currently have an operational program. In the vast majority of these programs, prescribers and pharmacists (herein referred to collectively as providers) can register to become an authorized user of the PDMP. Following authorization, users can then conduct online queries to obtain prescription histories for their patients, a process that may take up to several minutes. For many providers, accessing patient prescription histories offers critical input that can inform their clinical decision-making. This process has shown promise in preventing prescribing to patients who appear to be abusing prescription medications or obtaining controlled substances prescribed by multiple providers without knowledge of the other prescriptions (referred as doctor shopping) while enabling appropriate prescribing and dispensing for legitimate patients, especially for pain medication.

However, for many providers, even the few minutes required to log on to the PDMP and query a patient's prescription history present a barrier to regular use. Moreover, gaps in patients' prescription histories due to limited interstate sharing of PDMP data has contributed to relatively slow rates of provider registration with and use of PDMPs. PDMP reports show that it often takes four or more years following the implementation of online PDMP access for registration in the state to reach 50% of the prescribers who write controlled substance prescriptions, thus limiting the potential impact of these programs. Various strategies have been proposed to increase provider use of PDMPs. For example, several states have recently passed legislation mandating provider registration with and use of the PDMP under certain circumstances. Many states have also initiated efforts to enroll providers in educational training programs on the value of using PDMP data to counteract the prescription drug overdose epidemic. The project described below takes a different approach to increasing provider use of PDMPs.

In an effort to increase provider utilization of PDMPs and to effectively reduce prescription drug abuse and overdose, the Substance Abuse and Mental Health Services Administration (SAMHSA) funded projects in nine states beginning in fiscal year (FY) 2012 and lasting for a period of two years through its PDMP Electronic Health Records (EHRs) Integration and Interoperability Expansion (PEHRIIE) cooperative agreement program. The goals of this program are to:

(1) Increase provider utilization of their state's PDMP by improving real-time access to PDMPs via the integration of PDMP data and/or access thereof within health information technologies (HIT) such as health information exchanges (HIEs), EHR systems, and/or pharmacy dispensing software (PDS). Ultimately, when providers access a patient's EHR, s/he will have automatic access to that patient's up-to-date prescription history within the course of their normal clinical workflow, thereby obviating the time and effort otherwise needed to access the PDMP and obtain this information separately from the patient's medical record. Similarly, when a pharmacist calls up patient information via the PDS, the patient's prescription history from the PDMP will be automatically compiled, allowing for expedited access and review prior to dispensing.

(2) Increase provider utilization of PDMP data by increasing the comprehensiveness and quality of PDMP data by increasing the interoperability of PDMPs across state lines. When providers access a patient's prescription history from his or her state PDMP (either directly or via the systems described above), data from other state PDMPs with which the home state PDMP is interoperable will be automatically included. By providing a more complete prescription history, PDMP data is expected to have greater utility in clinical decision-making, thus offering an inducement for providers to access and utilize PDMP data more frequently.

Both of these goals are expected to contribute to improving prescribing and dispensing practices, resulting in decreased prescription drug abuse and misuse and related health consequences such as fatal and non-fatal overdoses as well as lead to improvements in care.

Under the cooperative agreements issued by SAMHSA, the CDC is responsible for conducting a comprehensive process and outcomes evaluation of the PEHRIIE program. The evaluation team consists of health scientists on the Prescription Drug Overdose team within the Division of Unintentional Injury Prevention, National Center for Injury Control and Prevention at CDC, and two subject matter experts at the PDMP Center of Excellence at Brandeis University. The primary goals of the qualitative evaluation component of this work are:

(1) To understand the processes, challenges, and successes in implementing and sustaining integration of PDMP data with Health Information Technology (HIT) systems and interoperability of PDMP systems across states; and

(2) To understand the experiences of clinical end users with the systems being upgraded under the PEHRIIE program and to capture their recommendations, if any, for how the goals of the PEHRIIE could have been better accomplished.

To achieve these evaluation goals, the CDC evaluation team will conduct qualitative interviews with those individuals involved in the planning and implementation of the PEHRIIE projects (i.e., key project staff and stakeholders) as well as with the clinical end users (i.e., prescribers and

pharmacists) of the PDMPs in the states where these projects are taking place.

This evaluation is consistent with CDC's strategic goals of improving surveillance, informing policy, and improving clinical practice. CDC believes that the most effective interventions in combating the prescription drug overdose epidemic include those designed to identify and address high-risk patients at a stage when their risky behaviors can be most effectively addressed. Strong yet accessible PDMPs that promote proactive patient interventions are a critical component of this high-risk focused strategy. By enabling providers to identify high-risk patients at the point of care, via improved access to and use of PDMPs and improved comprehensiveness of PDMP data, providers can intervene with patients and address their high-risk behaviors, including providing or redirecting patients to substance abuse treatment as necessary. Through this evaluation, CDC will better understand the impact of PDMP integration and interoperability in the funded states.

The total annual estimated burden hours for the planned qualitative information collection are 235 hours. Total burden time includes the time to conduct interviews with key project staff/stakeholders and clinical end users, and the time spent by recruiters at the PEHRIIE implementation sites to identify potential clinical end user interviewees.

It will take 79 hours of interviewee time to complete all of the key project staff/stakeholder interviews necessary for the planned evaluation of the PEHRIIE program. Interviews will be conducted with 91 key project staff members/stakeholders across the nine PEHRIIE-funded states (range: 6–16 interviews per state) as well as 14 key project staff/stakeholders representing five companies working with multiples states involved in the PEHRIIE program, for a total of 105 key project staff/stakeholders interviewees. Based on pilot testing with three individuals, each key project staff/stakeholder interview will take approximately 45 minutes to complete. Therefore, 105 key project staff/stakeholder interviews at 45 minutes each will require 79 hours of interviewee time.

It will take 117 hours of interviewee time to complete all of the clinical end user interviews necessary for the planned evaluation of the PEHRIIE program. Each interviewee will be interviewed once. End user interviews will be conducted at 39 implementation sites distributed across all nine PEHRIIE states (range: 3–8 sites per state). Interviews will be conducted with three clinical end users per implementation site for a total of 117 clinical end user interviews. Based on pilot testing with three individuals, each clinical end user interview will take one hour to complete. Therefore, 117 clinical end users at 1 hour each will require 117 hours of interviewee time.

It will take 39 hours of recruiter time to identify potential clinical end user interviewees, to collect the contact information from these clinical end users, and to disseminate this collected information to the CDC evaluation time. The CDC will work with one recruiter per implementation site to complete these tasks. Based on the time required to complete similar tasks during the planning of the clinical end user pilot interviews, each recruiter is expected to spend approximately one hour on these tasks. Therefore, 39 recruiters spending one hour each on this information collection will require 39 hours of recruiter time.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden (in hrs)
Key Project Staff/Stakeholders	Key Project Staff/Stakeholders Interview Guide.	105	1	45/60	79
Clinical End Users	Clinical End Users Interview Guide	117	1	1	117
Clinical End User Recruiters	N/A	39	1	1	39
Total					235

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–17295 Filed 7–18–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Income Withholding Order/Notice for Support (IWO).

OMB No.: 0970–0154.

Description: Statutory requirements under subsections 466(a)(1), (a)(8) and 466(b)(6) of the Social Security Act require the use of the Income Withholding for Support (IWO) form in all child support cases. The form must be used by child support agencies, courts, tribes, private attorneys and other entities when ordering or sending notices to withhold. 42 U.S.C 666(a)(1) and (8); 42 U.S.C 666(b)(6).

The Income Withholding for Support (IWO) form previously approved by the Office of Management and Budget has been modified to address items identified by states and employers/income withholders. The title of the form is changed to Income Withholding Order/Notice for Support (IWO) to correspond to the first line of the form. The blank box for court use is removed and text shifted to make better use of available space. Language is inserted to explain that provisions of the Consumer Credit Protection Act (CCPA) apply only to employees and not to independent contractors. A header with case-identifying information is added on Page Two and a Social Security Number on Page Three to place case-identifying information on each page and allow future automated improvements for employers and states. Clarifications are added to the Instructions emphasizing that each IWO should represent the information for only one case, as defined in the Code of Federal Regulations.

Respondents: Not applicable.

ANNUAL BURDEN ESTIMATES

Reporting requirement	Number of respondents	Number of responses per respondent	Annual number of responses	Average burden hours per response	Total burden hours
Employers	1,283,965	7.44	9,552,699.60	2 minutes	318,423
Non-IV–D CPs	2,436,312	1.00	2,436,312.00	5 minutes	203,026
e IWO Employers	4,763	131.75	627,525.25	3 seconds	523
Total	3,721,508		12,052,319		521,449

Estimated Total Annual Burden Hours: 521,449

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–17331 Filed 7–18–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0815]

Narcolepsy Public Meeting on Patient-Focused Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for narcolepsy. Patient-Focused Drug Development is part of FDA's performance commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients' perspectives on the impact of narcolepsy on daily life as well as the available therapies for narcolepsy.

DATES: The public meeting will be held on September 24, 2013, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by September 13, 2013. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting. Submit electronic or written comments by November 25, 2013.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Section A of the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

Submit electronic comments to *www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at: *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm359018.htm*.

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1170, Silver Spring, MD 20993, 301–796–0684, FAX: 301–847–8443, email: *Pujita.Vaidya@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected narcolepsy to be the focus of a meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA's performance commitments made as part of the authorization of PDUFA under Title I of the Food and Drug Safety and Innovation Act (FDASIA) (Pub. L. 112–144). The full set of performance commitments is available on the FDA Web site at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf*.

FDA has committed to obtain the patient perspective in 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a notice in the **Federal Register** (78 FR 22613) announcing the disease areas for meetings in fiscal years (FY) 2013–2015, the first 3 years of the 5-year PDUFA V timeframe. To develop the list of disease areas, the Agency used several criteria that were outlined in the April 11 notice. The Agency gathered public comment on these criteria and potential disease areas through a notice for public comment published in the **Federal Register** on September 24, 2012 (77 FR 55849), and through a public meeting

held on October 25, 2012. In selecting the disease areas, FDA carefully considered the public comments received and the perspectives of its review divisions. By the end of FY 2015, FDA will initiate another public process for determining the disease areas for FY 2016–2017. More information, including the list of disease areas and a general schedule of meetings, is posted on FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm*.

II. Public Meeting Information

A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will gather patient and patient stakeholder input on symptoms of narcolepsy that matter most to patients and on current approaches to treating narcolepsy. Narcolepsy is a chronic disorder of the central nervous system caused by the brain's inability to control sleep-wake cycles and is characterized by excessive daytime sleepiness, cataplexy, hallucination, and disturbed nocturnal sleep. Although there is no cure for narcolepsy, medications and lifestyle modifications can help patients manage their symptoms. FDA is interested in obtaining a better understanding of patients' perspectives on the severity of the disease and assessments of available therapies.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief patient panel discussion will begin the dialogue, followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through the public docket (see **ADDRESSES**).

Topic 1: Disease symptoms and daily impacts that matter most to patients:

1. Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include excessive daytime sleepiness, cataplexy, etc.)

2. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include sleeping through the night, work and school performance, etc.)

3. How have your symptoms changed over time?

3.1. Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?

Topic 2: Patients' perspectives on current approaches to treating narcolepsy:

1. What are you currently doing to help treat your condition or its symptoms? (Examples may include FDA-approved medicines, over-the-counter products, and other therapies including non-drug therapies such as lifestyle modifications.)

1.1. What specific symptoms do your therapies address?

1.2. How has your treatment regimen changed over time, and why?

2. How well does your current treatment regimen treat the most significant symptoms of your disease?

2.1. How well do these therapies improve your ability to do specific activities that are important to you in your daily life?

2.2. How well have these therapies worked for you as your condition has changed over time?

3. What are the most significant downsides to your current therapies, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, inconvenient dosing schedules, access issues, etc.)

4. Assuming there is no complete cure for your condition, what specific things would you look for in an ideal therapy for your condition?

B. Meeting Attendance and/or Participation

If you wish to attend this meeting, visit *http://patientfocused narcolepsy.eventbrite.com.* Please register by September 13, 2013. Those who are unable to attend the meeting in person can register to view a live webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend in person or via the webcast. Your registration should also contain your complete contact information, including name, title, affiliation, address, email address, and phone number.

Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of disability, please contact Pujita Vaidya (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. They will also be asked to send a brief summary of responses to the topic questions to *PatientFocused@fda.hhs.gov.* Panelists will be notified of their selection soon after the close of registration on September 13, 2013. FDA will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Interested members of the public, including those who attend the meeting in person or through the webcast, are invited to provide electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**). Comments may be submitted until November 25, 2013.

Dated: July 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17327 Filed 7–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0845]

Bracco Diagnostics et al.; Withdrawal of Approval of 52 New Drug Applications and 77 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 52 new drug applications (NDAs) and 77 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective August 19, 2013.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in

table 1 in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1

Application No.	Drug	Applicant
NDA 011620	Cardiografin (diatrizoate meglumine USP, 85%) Injection	Bracco Diagnostics, 107 College Rd. East, Princeton, NJ 08540.
NDA 012828	Travase (sutilains) Ointment	Abbott Laboratories, PA 77/Bldg. AP30–1E, 200 Abbott Park Rd., Abbott Park, IL 60064–6157.
NDA 014215	Celestone (betamethasone) Oral Solution	Merck Sharp & Dohme Corp., One Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889.
NDA 014685	Aventyl (nortriptyline hydrochloride (HCl) Oral Solution, 10 milligrams (mg)/5 milliliters (mL).	Ranbaxy Inc., U.S. Agent for Ranbaxy Laboratories Limited, 600 College Rd. East, Princeton, NJ 08540.
NDA 014860	Aralen Phosphate (chloroquine phosphate) with primaquine phosphate Tablets.	Sanofi-Aventis U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807–0890.
NDA 016017	Cloroquine-Primaquine (chloroquine phosphate and primaquine phosphate) Tablets.	Do.
NDA 016019	Questran Resin (cholestyramine resin)	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 016640	Questran Powder (cholestyramine for oral suspension)	Do.
NDA 016721	Dalmane (flurazepam HCl) Capsules	Valeant Pharmaceuticals North America, LLC, 700 Route 202/206 North, Bridgewater, NJ 08807.
NDA 016732	Talwin 50 (pentazocine HCl USP), Tablets, 50 mg	Sanofi-Aventis U.S., LLC.
NDA 016891	Talwin Compound (pentazocine HCl USP and aspirin USP), Equivalent to (EQ) 12.5 mg (base) and 325 mg.	Do.
NDA 016927	Demulen 1/50–21 (ethynodiol diacetate/ethinyl estradiol) Tablets.	G.D. Searle, LLC, c/o Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 016936	Demulen 1/50–28 (ethynodiol diacetate/ethinyl estradiol) Tablets.	Do.
NDA 017557	Danocrine (danazol) Capsules	Sanofi-Aventis U.S., LLC.
NDA 017633	Glycine Irrigation USP, 1.5%	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045.
NDA 017821	Flexeril (cyclobenzaprine HCl) Tablets, 5 mg and 10 mg	Janssen Research & Development, LLC, 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 017850	Klotrix (potassium chloride) Extended-Release Tablets	Bristol-Myers Squibb Co.
NDA 017857	Stadol (butorphanol tartrate USP) Injection	Do.
NDA 018160	Demulen 1/35–28 (ethynodiol diacetate/ethinyl estradiol) Tablets.	G.D. Searle, LLC, c/o Pfizer Inc.
NDA 018168	Demulen 1/35–21 (ethynodiol diacetate/ethinyl estradiol) Tablets.	Do.
ANDA 018398	Dopamine HCl Injection USP, 40 mg/mL and 80 mg/mL	Baxter Healthcare Corp., 25212 W. Illinois Route 120, Round Lake, IL 60073.
NDA 018458	Talacen (pentazocine HCl USP and acetaminophen USP), Tablets, EQ 25 mg (base) and 650 mg.	Sanofi-Aventis U.S., LLC.
ANDA 018581	Sodium Nitroprusside for Injection USP, 50 mg/vial	Baxter Healthcare Corp.
NDA 018733	Talwin Nx (pentazocine HCl and naloxone HCl) Tablets, 50 mg and 0.5 mg.	Sanofi-Aventis U.S., LLC.
NDA 018981	Enkaid (encainide HCl) Capsules	Bristol-Myers Squibb Co.
NDA 019057	Hytrin (terazosin HCl) Tablets, 1 mg, 2 mg, 5 mg, and 10 mg.	Abbott Laboratories.
NDA 019436	Primacor (milrinone lactate) Injection, EQ 1 mg (base)/mL	Sanofi-Aventis U.S., LLC.
NDA 019507	Kerlone (betaxolol HCl) Tablets, 10 mg and 20 mg	Do.
NDA 019578	Mefloquine HCl Tablets, 250 mg	U.S. Army Office of the Surgeon General, Department of the Army, 1430 Veterans Dr., Fort Detrick, MD 21702–5009.
NDA 019669	Questran Light, Questran II, and Questran Sugar Free (cholestyramine for oral suspension).	Bristol-Myers Squibb Co.
NDA 019807	Kerledex (betaxolol HCl and chlorthalidone) Tablets	Sanofi-Aventis U.S., LLC.
NDA 019977	Oramorph SR (morphine sulfate) Sustained-Release Tablets, 15 mg, 30 mg, 60 mg, and 100 mg.	Xanodyne Pharmaceuticals, Inc., One Riverfront Pl., Newport, KY 41071.
NDA 020036	Aredia (pamidronate disodium) for injection, 30 mg, 60 mg, and 90 mg.	Novartis Pharmacueticals Corp., One Health Plaza, East Hanover, NJ 07936–1080.
NDA 020038	Fludara (fludarabine phosphate) for Injection, 50 mg/vial	Genzyme Corp., 500 Kendall St., Cambridge, MA 02142.
NDA 020056	Atropine Sulfate Aerosol for Inhalation	U.S. Army Office of the Surgeon General.
NDA 020070	Cognex (tacrine HCl) Capsules, 10 mg, 20 mg, 30 mg, and 40 mg.	Shionogi Inc., 300 Campus Dr., Florham Park, NJ 07932.
NDA 020095	Zantac (ranitidine HCl) Geldose Capsules	GlaxoSmithKline, P.O. Box 13398, 5 Moore Dr., Research Triangle Park, NC 27709.
NDA 020151	Effexor (venlafaxine HCl) Tablets, 12.5 mg, 25 mg, 37.5 mg, 50 mg, 75 mg, and 100 mg.	Wyeth Pharmaceuticals, Inc., 235 East 42nd St., New York, NY 10017.
NDA 020239	Kytril (granisetron HCl) Injection, EQ 1 mg (base)/mL and 0.1 mg (base)/mL, 1 mg (base)/mL, and 3 mg (base)/mL.	Hoffman-La Roche, Inc., c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 020305	Kytril (granisetron HCl) Tablets, EQ 1 mg (base), EQ 2 mg (base).	Do.
NDA 020336	DynaCirc CR (isradipine) Controlled-Release Tablets	GlaxoSmithKline, 2301 Renaissance Blvd., King of Prussia, PA 19406.
NDA 020343	Primacor (milrinone lactate) Injection	Sanofi-Aventis U.S., LLC.
NDA 020347	Hytrin (terazosin HCl) Capsules, 1 mg, 2 mg, 5, mg, and 10 mg.	Abbott Laboratories.
NDA 020441	Pulmicort Turbuhaler (budesonide) Inhalation Powder	AstraZeneca, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355.
NDA 020484	Innohep (tinzaparin sodium) Injection	LEO Pharma A/S, c/o Parexel International Corp., 4600 East-West Highway, Suite 350, Bethesda, MD 20814.
NDA 020611	Dovonex (calcipotriene) Topical Solution, 0.005%	LEO Pharma A/S, c/o LEO Pharma Inc., 1 Sylvan Way, Parsippany, NJ 07054.
NDA 020680	Norvir (ritonavir) Capsules, 100 mg	Abbott Laboratories.
NDA 021238	Kytril (granisetron HCl) Oral Solution, 2 mg/10 mL	Hoffman-La Roche, Inc., c/o Genentech, Inc.
NDA 021320	Plenaxis (abarelix) Injection, 100 mg/vial	Specialty European Pharma Limited, c/o Strategic Bioscience Corp., 93 Birch Hill Rd., Stow, MA 01775.
NDA 021744	Proquin XR (ciprofloxacin HCl) Tablets, 500 mg	Depomed Inc., 1360 O'Brien Dr., Menlo Park, CA 94025.
NDA 022021	Altace (ramipril) Tablets, 1.25 mg, 2.5 mg, 5 mg, and 10 mg.	King Pharmaceuticals Inc., c/o Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 022026	Amlodipine Besylate Orally Disintegrating Tablets, 2.5 mg, 5 mg, and 10 mg.	Synthon Pharmaceuticals, Inc., 9000 Development Dr., P.O. Box 110487, Research Triangle Park, NC 27709.
NDA 022456	Omeprazole, Sodium Bicarbonate, and Magnesium Hydroxide Tablets.	Santarus, Inc., 3721 Valley Centre Dr., Suite 400, San Diego, CA 92130.
ANDA 040015	Neosar (cyclophosphamide) for Injection, 100 mg, 200 mg, 500 mg, 1 gram (gm), and 2 gm vials.	Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618.
ANDA 040079	Thiamine HCl Injection USP, 100 mg/mL	Hospira, Inc.
ANDA 040131	Edrophonium Chloride Injection, 10 mg/mL	Do.
ANDA 040162	Prochlorperazine Maleate Tablets USP, 5 mg and 10 mg	IVAX Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 040272	Oxycodone and Acetaminophen Tablets USP, 5 mg/325 mg.	Duramed Pharmaceuticals, Inc., Subsidiary of Barr Laboratories, Inc., Indirect Wholly Owned Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 040332	Leucovorin Calcium Injection USP, 10 mg (base)	Teva Parenteral Medicines, Inc.
ANDA 040364	Prednisolone Syrup, 15 mg/5 mL	Nesher Pharmaceuticals (USA) LLC, 13910 Saint Charles Rock Rd., Bridgton, MO 63044.
ANDA 040373	Hydralazine HCl Injection USP, 20 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 040423	Prednisolone Syrup, 5 mg/5 mL	Nesher Pharmaceuticals (USA) LLC.
ANDA 040505	Prochlorperazine Edisylate Injection USP, 5 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 040641	Methylprednisolone Sodium Succinate for Injection USP, 125 mg/vial, 500 mg/vial, and 1 gm/vial.	Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146.
ANDA 040662	Methylprednisolone Sodium Succinate for Injection USP, 40 mg/vial.	Do.
ANDA 040709	Methylprednisolone Sodium Succinate for Injection USP, 500 mg/vial and 1 gm/vial.	Do.
ANDA 040795	Benzonatate Capsules USP, 100 mg and 200 mg	Nesher Pharmaceuticals (USA) LLC.
ANDA 040909	Sodium Polystyrene Sulfonate Powder for Suspension, 454 gm/bottle.	Citrus Pharma, LLC, 3940 Quebec Ave. North, Minneapolis, MN 55427.
NDA 050261	Declomycin (demeclocycline HCl) Tablets, 75 mg, 150 mg, and 300 mg.	CorePharma, LLC, 215 Wood Ave., Middllesex, NJ 08846–2554.
ANDA 060003	V-Cillin K (pencillin V potassium tablets USP), 125 mg, 250 mg, and 500 mg.	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
ANDA 060517	Fugizone (amphotericin B) for Injection	Bristol-Myers Squibb Co.
ANDA 060575	Mycostatin (nystatin) Cream, 100,000 units/gm	Do.
ANDA 061901	Kantrex (kanamycin sulfate injection USP) Injection,75 mg/2 mL, 500 mg/2 mL, and 1 gm/3 mL.	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80038–0446.
ANDA 062008	Nebcin (tobramycin for injection USP)	Eli Lilly and Co.
ANDA 062311	Amikin (amikacin sulfate injection USP), 50 mg/mL and 250 mg/mL.	Brisol-Myers Squibb Co.
ANDA 062707	Nebcin (tobramycin for injection USP)	Eli Lilly and Co.
ANDA 063041	Clindamycin Injection USP	Teva Parenteral Medicines, Inc.
ANDA 063080	Tobramycin Injection USP	Hospira, Inc.
ANDA 063149	Gentamicin Injection USP, 10 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 063282	Clindamycin Phosphate Injection, EQ 150 mg (base)/mL	Do.
ANDA 063253	Erythromycin Lactobionate for Injection USP, 500 mg (base)/vial and 1 gm (base)/vial.	Do.
ANDA 064021	Tobramycin Sulfate Injection	Bristol-Myers Squibb Co.
	Amphotericin B for Injection USP, 50 mg/vial	Teva Parenteral Medicines, Inc.
ANDA 064212	Daunorubicin HCl for Injection USP, 20 mg (base)/vial and 50 mg (base)/vial.	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 065037	Idarubicin HCl for Injection USP, 5 mg/vial, 10 mg/vial, and 20 mg/vial.	Do.
ANDA 065321	Nystatin Topical Powder USP, 100,000 units/gm	Nesher Pharmaceuticals (USA) LLC.
ANDA 065433	Mycophenolate Mofetil Capsules, 250 mg	Zydus Pharmaceuticals (USA) Inc., 73 Route 31 North, Pennington, NJ 08534.
ANDA 065477	Mycophenolate Mofetil Tablets, 500 mg	Do.
ANDA 070159	Tolazamide Tablets USP, 100 mg	Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977.
ANDA 070160	Tolazamide Tablets USP, 250 mg	Do.
ANDA 070161	Tolazamide Tablets USP, 500 mg	Do.
ANDA 070431	Valproic Acid Capsules, 250 mg	Do.
ANDA 070577	Verapamil HCl Injection USP, 2.5 mg/mL	Hospira, Inc.
ANDA 070818	Ibuprofen Tablets USP, 400 mg	Ohm Laboratories, c/o Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540.
ANDA 070980	Potassium Chloride Extended-Release Capsules USP, 10 milliequivalents.	Nesher Pharmaceuticals (USA) LLC.
ANDA 071200	Disopyramide Phosphate Extended-Release Capsules USP, 150 mg.	Do.
ANDA 071726	Metaproterenol Sulfate Inhalation Solution, 0.6%	Nephron Pharmaceuticals Corp., 4121 South West 34th St., Orlando, FL 32811.
ANDA 071855	Metaproterenol Sulfate Inhalation Solution, 0.4%	Do.
ANDA 072273	Albuterol Inhalation Aerosol[1]	Armstrong Pharmaceuticals, Inc. 25 John Rd., Canton, MA 02021.
ANDA 072437	Fenoprofen Calcium Capsules USP, 200 mg	Par Pharmaceuticals, Inc.
ANDA 072974	Methyldopate HCl Injection USP	Teva Parenteral Medicines, Inc.
ANDA 073000	Dopamine HCl Injection USP, 80 mg/mL	Do.
ANDA 073117	Metoclopramine Injection USP, 5 mg/mL	Hospira, Inc.
ANDA 073465	Sodium Nitroprusside Injection, 25 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 073617	Pentamidine Isethionate for Injection, 300 mg/vial	Baxter Healthcare Corp.
ANDA 073683	Cyclobenzaprine HCl Tablets, 10 mg	Sandoz Inc.
ANDA 074013	Pindolol Tablets USP, 5 mg	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26505–4310.
ANDA 074018	Pindolol Tablets USP, 10 mg	Do.
ANDA 074105	Naproxen Tablets USP, 250 mg, 375 mg, and 500 mg	DAVA Pharmaceuticals, Inc., Parker Plaza, 400 Kelby St., 10th Floor, Fort Lee, NJ 07024.
ANDA 074147	Metoclopramide Injection USP, 5 mg/mL	Hospira, Inc.
ANDA 074206	Dobutamine Injection USP, 250 mg (base)/20 mL	Teva Parenteral Medicines, Inc.
ANDA 074252	Cimetidine HCl Injection, EQ 300 mg (base)/2 mL	Do.
ANDA 074519	Captopril Tablets, 12.5 mg, 25 mg, 50 mg, and 100 mg	Sandoz Inc.
ANDA 074613	Bumetanide Injection USP, 0.25 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 074616	Inamrinone Lactate Injection, 5 mg/mL	Hospira, Inc.
ANDA 074629	Iopamidol Injection USP, 41%, 51%, 61%, and 76%	Baxter Healthcare Corp.
ANDA 074637	Iopamidol Injection USP, 61%	Hospira, Inc.
ANDA 074753	Atracurium Besylate Injection USP, 10 mg/mL (preserved)	Baxter Healthcare Corp.
ANDA 074768	Atracurium Besylate Injection USP, 10 mg/mL (preservative free).	Do.
ANDA 074784	Atracurium Besylate Injection USP, 10 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 074795	Fluphenazine Decanoate Injection USP, 25 mg/mL	Do.
ANDA 074969	Acyclovir for Injection USP, 500 mg/vial and 1,000 mg/vial	Do.
ANDA 075004	Diltiazem HCl Injection, 5 mg/mL	Hospira, Inc.
ANDA 075005	Iopamidol Injection USP, 51%, 61%, and 76%	Do.
ANDA 075012	Etodolac Tablets USP, 400 mg and 500 mg	Mylan Pharmaceuticals, Inc.
ANDA 075071	Etodolac Capsules, 200 mg and 300 mg	Do.
ANDA 075119	Buspirone HCl Tablet USP, 5 mg, 10 mg, and 15 mg	Egis Pharmaceuticals PLC, c/o GlobePharm Inc., 313 Pine St., Suite 204, Deerfield, IL 60015.
NDA 075166	Isosorbide Mononitrate Extended-Release Tablets, 60 mg	SkyePharma AG, c/o Compliance Resources, LLC, 7100 Farmington Lane, Hillsborough, NC 27278.
ANDA 075328	Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg	Vintage Pharmaceuticals, 120 Vintage Dr., Huntsville, AL 35811.
ANDA 075392	Propofol Injectable Emulsion, 10 mg/mL	Teva Parenteral Medicines, Inc.

[1] This product included an oral pressurized metered-dose inhaler that contained chlorofluorocarbons (CFCs) as a propellant. CFCs may no longer be used as a propellant for any albuterol metered-dose inhalers (see 70 FR 17168, April 4, 2005).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective August 19, 2013. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see

DATES) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: July 15, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2013–17324 Filed 7–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request Evaluation of a Kidney Disease Education and Awareness Program in the Hispanic Community

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Kidney Disease Education Program, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Eileen Newman, Associate Director, National Kidney Disease Education Program, OCPL, NIDDK, NIH, Building 31, Room 9A06, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number 301–435–8116 or Email your request, including your address to: *Eileen.newman@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Evaluation of a Kidney Disease Education Program with Promotores in the Hispanic Community, 0925–NEW, National Kidney Disease Education Program, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH).

Need and Use of Information Collection: NKDEP is developing a kidney disease education program to raise awareness among the Hispanic community at risk for kidney disease. Since diabetes is the most common cause of kidney disease, the program is being developed for inclusion in existing diabetes programs being conducted by ''promotores de salud'' (Spanish/English-speaking community health workers). A pilot evaluation will assess: (a) Overall quality of the program from the client and promotor/a perspective, including strengths and weaknesses of the program and the training, and areas for program improvement; (b) effectiveness of the program on the clients (the community members being educated); and (c) effectiveness of materials and training, including promotores' ability to deliver education to the client and administer the client pre-test/post-test surveys. The pilot study will deliver strategic and actionable guidance for refining the educational and training materials for national dissemination. Based on outcomes from the pilot study, a national evaluation is planned that will use the client pre-test/post-test surveys to assess: (a) Knowledge gains about kidney disease, (b) awareness of NKDEP resources and importance of kidney health, (c) reported behavior change outcomes and (d) reported health status.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 101 (see table below).

TABLE A.12.A—ESTIMATE ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Response burden (hours)	Total burden hours
Pilot study collection:					
Promotores	Promotores training pre-test, post-test, and qualitative in-depth interview post client session (Attachment 1 and 2).	12	1	5/60	1
Promotores	Administer client pre-test, post-test, and second post-tests for experimental and control groups (Attachment 3).	20	17	15/60	85
Client Group	Client pre-test, post-test, second post-test for experimental and control groups (Attachment 3).	85	1	10/60	14
Client Group (partial)	Client qualitative in-depth interview post-client session (Attachment 4).	4	1	10/60	1
Total		121			101

Dated: July 10, 2013.

Ruby N. Akomeah,

Project Clearance Liaison, NIDDK, NIH.

[FR Doc. 2013–17365 Filed 7–18–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day Comment Request: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 23, 2013, Vol. 78, page 23942 and allowed 60-days for public comment. One public comment was received on April 23, 2013, that questioned spending taxpayer money for this research. An email response was sent on April 24, 2013, stating, ''We received your comment. We will take your comments into consideration''. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Jane Hoppin, Sc.D., Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, PO Box 12233, MD A3–05, Research Triangle Park, NC 27709, or call non-toll-free number 919–541–7622, or email your request, including your address to: *hoppin1@niehs.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture, 0925–0406—REVISION—National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this information collection is to request initiation of a new dust specimen component as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA) as well as continue and complete phase IV (2013–2015) of the Agricultural Health Study (AHS) and continue buccal cell collection. Phase IV will continue to update the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the AHS. The new BEEA dust component will include a brief paper-and-pen questionnaire mailed to the participant in advance of the home visit; at the home visit, the study phlebotomist will to collect and review the questionnaire, and collect the participant's disposable vacuum bag (or empty the dust from vacuums without disposable bags). The dust component will use similar procedures to ones that have been employed on other NCI studies to obtain information about the dust specimen and to collect and ship the dust specimen. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer. Phase IV questionnaire data are collected by using self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents are also asked to participate in the collection of biospecimens and environmental samples, including blood, urine, buccal cells (loose cells from the respondent's mouth), and vacuum dust. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among Agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 10,679.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Reminder, Missing, and Damaged Scripts for Buccal Cell.	Private and Commercial Applicators and Spouses.	100	1	5/60	8
BEEA CATI Eligibility Script	Private Applicators	480	1	20/60	160
Mailed Consent, Pre-Visit Show Card, and Paper/Pen Dust Questionnaire.	Private Applicators	160	1	20/60	53
BEEA Home Visit CAPI, Blood, Urine, & Dust x 1.	Private Applicators	160	1	90/60	240
BEEA Schedule Home Visit Scripts	Private Applicators	20	3	5/60	5
BEEA Home Visit CAPI, Blood, & Urine x 3.	Private Applicators	20	3	30/60	30
Paper/pen, CAWI or CATI	Private Applicators	13,855	1	25/60	5,773

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Paper/pen, CAWI or CATI	Spouses	10,201	1	25/60	4,250
Paper/pen, CAWI or CATI	Proxy	635	1	15/60	159

Dated: July 10, 2013.

Rick Woychik,

Deputy Director, NIEHS.

[FR Doc. 2013–17362 Filed 7–18–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Use of Cysteamine to Treat Metastatic Cancer

Description of Technology: Cysteamine is an aminothiol and anti-oxidant that has potential for the treatment of radiation sickness, neurological disorders and cancer. Cysteamine has FDA approval for use in humans, and produces few side-effects as a natural degradation product of an essential amino acid. It is mostly used for treatment of cystinosis. The inventors on this technology have demonstrated that cysteamine also suppresses the activity of matrix metalloproteinases (MMPs). Because MMPs have been implicated in tumor invasion and metastasis, cysteamine has potential as an effective therapeutic for metastatic cancer. Administration of cysteamine was able to reduce invasion and metastasis in mouse xenograft tumor models and prolong survival of the mice without significant adverse side effects. This suggests that cysteamine could represent a novel therapeutic agent for treatment of metastatic cancer.

Potential Commercial Applications: Therapeutic for metastatic cancer as monotherapy or combined with other drugs.

Competitive Advantages:

- Cysteamine does not produce adverse side-effects when administered to humans.
- Cysteamine has already been approved for use in humans, providing a clearer path to clinical approval.

Development Stage:

- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Raj K. Puri and Bharat Joshi (CBER/FDA).

Publication: Fujisawa T, et al. Cysteamine suppresses invasion, metastasis and prolongs survival by inhibiting matrix metalloproteinases in a mouse model of human pancreatic cancer. PLoS One. 2012;7(4):e34437. [PMID 22532830]

Intellectual Property: HHS Reference No. E–219–2013/0—

- US Provisional Application No. 61/814,010.
- Canadian Application No. 2813514.
- Australian Application No. 2013205350.
- Korean Application No. 10–2013–43713.

Licensing Contact: David A. Lambertson, Ph.D.; 301–435–4632; *lambertsond@mail.nih.gov*.

Encircling Suture Delivery System

Description of Technology: The invention provides a novel delivery system for delivering an encircling suture which includes two separate hollow limbs held together at an articulation by the suture to be delivered. The suture can extend through the hollow limbs, which slide along the suture. The distal ends of the limbs can be compressed into a desired delivery shape that allows the limbs to be advanced through the lumen of a delivery catheter (e.g., a transcutaneous, transvascular or intraluminal catheter) into any body cavity. As the distal portions of the limbs move out of the delivery catheter, the limbs cooperatively assume a loop shape complementary to the shape of the target around the encircling suture to leave only the suture in the desired delivery position while maintaining desired suture tension and position. The delivery device can be placed around a variety of anatomical structures (e.g., heart, arterial appendage, cecal appendix, gall bladder, neoplasm, uterus, hemorrhoid, uvula, aneurysm, transected blood vessel, folded or looped lumen, intraocular crystalline lens or implated intraocular lens or haptic, urinary bladder, kidney, prostate, intestine, or liver, etc.).

Potential Commercial Applications:

- Surgery.
- Suturing.
- Catheterization.
- Cardiac valve repair.

Competitive Advantages:

- Formable suturing.
- Circumferential suturing.
- Flexible.
- Easy to use.

Development Stage: Prototype.

Inventors: Toby Rogers, Robert Lederman, Merdim Sonmez, Dominique Franson, Ozgur Kocaturk (all of NHLBI).

Intellectual Property: HHS Reference No. E–115–2013/0—US Provisional Patent Application 61/834,357 filed June 12, 2013.

Related Technologies:

- HHS Reference No. E–027–2013/0—Devices and Methods for Treating Functional Tricuspid Valve Regurgitation.
- HHS Reference No. E–112–2010/0—Target and Capture Device for Transcatheter Cerclage Annuloplasty.
- HHS Reference No. E–108–2010/0—An Expandable Mesh Target and Capture Device for Transcatheter Cerciage Annuloplasty.

Licensing Contact: Michael Shmilovich; 301–435–5019; *shmilovm@mail.nih.gov.*

Peptide Inhibitors of Polo-like Kinase 1 (PLK1) Useful as Anti-cancer Therapeutics

Description of Technology: PLK1 is being studied as a target for cancer drugs. Many colon and lung cancers are caused by KRAS mutations. These cancers are dependent on PLK1. Inhibition of PLK1 allows for selective killing of cancer cells without harm to normal cells. The peptide derivatives available for licensing have achieved both good efficacy and enhanced bioavailability.

Potential Commercial Applications: Development of selective cancer therapeutics.

Competitive Advantages: Enhanced bioavailability and higher binding efficacy over existing peptide PLK1 ligands.

Development Stage: Early-stage.

Inventors: Terrence R. Burke, Fa Liu, Wen-Jian Qian, Jung-Eun Park, Kyung S. Lee (all of NCI).

Publications:

1. Liu F, et al. Serendipitous alkylation of a Plk1 ligand uncovers a new binding channel. Nat Chem Biol. 2011 Jul 17;7(9):595–601. [PMID 21765407].

2. Qian W, et al. Investigation of unanticipated alkylation at the N(π) position of a histidyl residue under Mitsunobu conditions and synthesis of orthogonally protected histidine analogues. J Org Chem. 2011 Nov 4;76(21):8885–90. [PMID 21950469].

3. Liu F, et al. Identification of high affinity polo-like kinase 1 (Plk1) polo-box domain binding peptides using oxime-based diversification. ACS Chem Biol. 2012 May 18;7(5):805–10. [PMID 22292814].

4. Liu F, et al. Peptoid-Peptide hybrid ligands targeting the polo box domain of polo-like kinase 1. Chembiochem. 2012 Jun 18;13(9):1291–6. [PMID 22570300].

5. Qian W, et al. Effects on polo-like kinase 1 polo-box domain binding affinities of peptides incurred by structural variation at the phosphoamino acid position. Bioorg Med Chem. 2013 Jul 15;21(14):3996–4003. [PMID 22743087].

6. Qian W, et al. Non-proteinogenic amino acids in the pThr–2 position of a pentamer peptide that confer high binding affinity for the polo box domain (PBD) of polo-like kinase 1 (Plk1). Bioorg Med Chem Lett. 2012 Dec 15;22(24):7306–8. [PMID 23159568].

Intellectual Property: HHS Reference No. E–094–2013/0—US Application No. 61/784,971 filed March 14, 2013.

Related Technologies: HHS Reference Nos. E–181–2009/0, E–181–2009/1, E–181–2009/3, E–181–2009/4, E–053–2012/0—Development of Peptide Mimetic Ligands of Polo-like Kinase 1 Polo Box Domain.

Licensing Contact: Patrick McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov*.

Polymeric Silicone Hydrogel Vessel Mimetics for Cell Culturing

Description of Technology: The invention pertains to high oxygen diffusivity silicone hydrogel support structures that mimic tissue vasculature (e.g., capillary bed). Photolithographic methods are used to construct mimetic silicone hydrogel pillars that have, for example, a 20:1 height to diameter ratio. Advantageously, these mimetic silicone hydrogels diffuse oxygen from the bottom chamber to the cells cultured on the surface at near physiological rates (60 times that of water). Uses of these mimetics include 2–D screening for chemotherapeutic compounds and growth of tissue for grafting.

Potential Commercial Applications:

- Tissue engineering.
- Simulation of physiological growth conditions.

Competitive Advantages: High oxygen diffusivity.

Development Stage:

- Prototype.
- Pilot.
- In vitro data available.

Inventors: Chandan Das (NCI), Ashley Jaeger (CIT), Thomas Pohida (CIT), Randall Pursley (CIT), Philip McQueen (CIT), Nicole Morgan (NIBIB), Michael Gottesman (NCI).

Intellectual Property:

- HHS Reference No. E–070–2013/0—US Provisional Patent Application 61/758,198 filed January 29, 2013.
- HHS Reference No. E–070–2013/1—US Provisional Patent Application 61/773,064 filed March 5, 2013.

Licensing Contact: Michael Shmilovich; 301–435–5019; *shmilovm@mail.nih.gov*.

Co-Transcriptional Assembly of Modified RNA Nanoparticles

Description of Technology: A method is provided for generating RNA nanoparticles having modified nucleotides and/or having increased nuclease resistance where the RNA nanoparticles are formed co-transcriptionally by T7 RNA polymerase in the presence of manganese ions.

Potential Commercial Applications: Inexpensive and efficient method of producing chemically modified RNA nanoparticles for diagnostic or therapeutic applications.

Competitive Advantages:

- Overcomes the cost and size limitations of solid-phase RNA synthesis.
- Allows complexity of RNA nanoparticles production.
- Increases retention time of RNA nanoparticles.

Development Stage:

- Early-stage.
- In vitro data available.

Inventors: Bruce A. Shapiro (NCI), Kirill Afonin (NCI), Maria Kireeva (NCI), Mikhail Kashlev (NCI), Luc Jaeger (Univ California, Santa Barbara), Wade Grabow (Univ California, Santa Barbara).

Publications:

1. Afonin KA, et al. Co-transcriptional assembly of chemically modified RNA nanoparticles functionalized with siRNAs. Nano Lett. 2012 Oct 10;12(10):5192–5. [PMID 23016824].

2. Grabow WW, et al. ''RNA Nanotechnology in Nanomedicine,'' in Nanomedicine and Drug Delivery (Recent Advances in Nanoscience and Nanotechnology), ed. M Sebastian, et al. (New Jersey: Apple Academic Press, 2012), 208–220. [Book Chapter].

3. Shukla GC, et al. A boost for the emerging field of RNA nanotechnology. ACS Nano. 2011 May 24;5(5):3405–18. [PMID 21604810].

4. Afonin KA, et al. Design and self-assembly of siRNA-functionalized RNA nanoparticles for use in automated nanomedicine. Nat Protoc. 2011 Dec 1;6(12):2022–34. [PMID 22134126].

5. Bindewald E, et al. Multistrand RNA secondary structure prediction and nanostructure design including pseudoknots. ACS Nano. 2011 Dec 27;5(12):9542–51. [PMID 22067111].

6. Grabow WW, et al. Self-assembling RNA nanorings based on RNAI/II inverse kissing complexes. Nano Lett. 2011 Feb 9;11(2):878–87. [PMID 21229999].

7. Kasprzak W, et al. Use of RNA structure flexibility data in nanostructure modeling. Methods. 2011 Jun;54(2):239–50. [PMID 21163354].

Intellectual Property: HHS Reference No. E–223–2012/0—US Provisional Application No. 61/698,227 filed 07 Sep 2012.

Related Technologies:

- HHS Reference No. E–059–2009/0—International Application No. PCT/US2010/038818.
- HHS Reference No. E–038–2012/0—International Application No. PCT/US2012/065932.
- HHS Reference No. E–039–2012/0—International Application No. PCT/US2012/065945.

Licensing Contact: John Stansberry; 301–435–5236; *stansbej@mail.nih.gov*.

Collaborative Research Opportunity: The NCI Center for Cancer Research Nanobiology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize diagnostic or therapeutic RNA nanoparticles. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Dated: July 12, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–17319 Filed 7–18–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Kidney Interagency Coordinating Committee Meeting

SUMMARY: The Kidney Interagency Coordinating Committee (KICC) will hold a meeting on September 27, 2013, about interagency collaboration to improve outcomes in Chronic Kidney Disease (CKD). The meeting is open to the public.

DATES: The meeting will be held on September 27, 2013, 9 a.m. to 12 p.m. Individuals wanting to present oral comments must notify the contact person at least 10 days before the meeting date.

ADDRESSES: The meeting will be held at the Natcher Conference Center (Building 45), on the NIH Campus at 8600 Rockville Pike, Bethesda, MD 20894.

FOR FURTHER INFORMATION CONTACT: For further information concerning this meeting, contact Dr. Andrew S. Narva, Executive Secretary of the Kidney Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 31 Center Drive, Building 31A, Room 9A26, MSC 2560, Bethesda, MD 20892–2560, telephone: 301–594–8864; FAX: 301–480–0243; email: *nkdep@info.niddk.nih.gov.*

SUPPLEMENTARY INFORMATION: The KICC, chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), comprises members of the Department of Health and Human Services and other federal agencies that support kidney-related activities, facilitates cooperation, communication, and collaboration on kidney disease among government entities. KICC meetings, held twice a year, provide an opportunity for Committee members to learn about and discuss current and future kidney programs in KICC member organizations and to identify opportunities for collaboration. The September 27, 2013 KICC meeting will focus on interagency collaboration to improve outcomes in CKD.

Any member of the public interested in presenting oral comments to the Committee should notify the contact person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives or organizations should submit a letter of intent, a brief description of the organization represented, and a written copy of their oral presentation in advance of the meeting. Only one representative of an organization will be allowed to present; oral comments and presentations will be limited to a maximum of 5 minutes. Printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the Committee by forwarding their statement to the contact person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Because of time constraints for the meeting, oral comments will be allowed on a first-come, first-serve basis.

Members of the public who would like to receive email notification about future KICC meetings should send a request to *nkdep@info.niddk.nih.gov.*

Dated: July 8, 2013.

Camille Hoover,

Executive Officer, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

[FR Doc. 2013–17360 Filed 7–18–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Immune Mechanism.

Date: July 30, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301–495–1506, *jakesse@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–OD–13–005: Restoration of New Investigator Pilot Projects Adversely Affected by Hurricane Sandy.

Date: August 14, 2013.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, *luow@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Vascular Hematology.

Date: August 14, 2013.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bukhtiar H Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, 301–806–7314, *shahb@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 15, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–17320 Filed 7–18–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Live Attenuated Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in the 3'-UTR of Dengue Types 1, 2, 3, and 4

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a an exclusive license to practice the following invention as embodied in the following patent applications: (1) E–120–2001/0, Whitehead et al., ''Development of Mutations Useful for Attenuating Dengue Viruses and Chimeric Dengue Viruses'', European Patent Application Number 02739358.6 (now European Patent Number 1402075, validated in Austria, Belgium, Switzerland/Liechtenstein, Germany, Denmark, Spain, Finland, France, the United Kingdom, Ireland, Italy, the Netherlands, Sweden and Turkey), filed May 22, 2002, United States Patent Application Number 10/719,547 (now U.S. Patent Number 7,226,602), filed November 21, 2003, Canadian Patent Application Number 2448329 (now Canadian Patent Number 2448329), filed May 22, 2002, Australian Patent Application Number 20022312011 (now Australian Patent Number 20022312011), filed May 22, 2002, Australian Patent Application Number 2008203275 (now Australian Patent Number 2008203275), filed May 22, 2002, Australian Patent Application Number 2012200637, filed May 22, 2002, United States Patent Application Number 11/446,050, filed June 2, 2006, now U.S. Patent Number 7,560,118, issued July 14, 2009, United States Patent Application Number 12/396,376 (now United States Patent Number 8,039,003), filed March 2, 2009, United States Patent Application Number 13/240,849, filed September 22, 2011, European Patent Application Number 10181776.5, filed May 22, 2002, European Patent Application Number 10181786.4, filed May 22, 2002, and European Patent Application Number 10181804.5, filed May 22, 2002 (2) E–089–2002/0,1, Whitehead et al., ''Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in The 3'-UTR of Dengue Types 1,2,3, And 4, or Antigenic Chimeric Dengue Viruses 1,2,3, And 4'', United States Patent Application Number 10/970,640 (now United States Patent Number 7,517,531), filed October 21, 2004, Canadian Patent Application Number 2483653, filed April 25, 2003, European Patent Application Number 03724319.3 (now European Patent Number 1554301, validated in Austria, Belgium, Bulgaria, Switzerland/Liechtenstein, Estonia, Finland, France, the United Kingdom, Ireland, Iceland, Italy, Lithuania, Malta, the Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, Turkey, Cyprus, Croatia, Czech Republic, Denmark, Germany, Greece, Hungary, Latvia, Luxembourg, and Monaco), filed April 25, 2003, Japanese Patent Application Number 2004–50077, filed April 25, 2003, Australian Patent Application 2003231185 (now Australian Patent Number 2003231185), filed April 25, 2003, United States Patent Application Number 12/398,043 (now United States Patent Number 8,075,903), filed March 4, 2009, United States Patent Application Number 13/305,639, filed November 28, 2011, European Patent Application Number 10177735.7, filed April 25, 2003, and European Patent Application Number 10177740.7, filed April 25, 2003, and (3) E–139–2006/0, Whitehead et al., ''Development of Dengue Vaccine Components'', Australian Patent Application 2007285929, filed August 15, 2007, Canadian Patent Application Number 2661296, filed August 15, 2007, Chinese Patent Application Number 200780031489.4, filed August 15, 2007, European Patent Application Number 07840969.5, filed August 15, 2007, United States Patent Application Number 12/376,756 (now U.S. Patent Number 8,337,860), filed February 6, 2009, and United States Patent Application Number 13/692,557, filed December 3, 2012 to Merck Sharp & Dohme Corp., having a place of business in Whitehouse Station, New Jersey, U.S.A. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before August 19, 2013 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Email: *ps193c@nih.gov;* Telephone: (301) 435–4646; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: The global prevalence of dengue has grown dramatically in recent decades. The disease is now endemic in more than 100 countries in Africa, North and South America, the Eastern Mediterranean, Southeast Asia and the Western Pacific. Southeast Asia and the Western Pacific are most seriously affected. Before 1970 only nine countries had experienced Dengue Hemorrhagic Fever (DHF) epidemics, a number that had increased more than four-fold by 1995. WHO currently estimates there may be 50 million cases of dengue infection worldwide every year.

The methods and compositions of this invention provide a means for prevention of dengue infection and dengue hemorrhagic fever (DHF) by immunization with attenuated, immunogenic viral vaccines against dengue. The vaccine is further described in Blaney JE et al., ''Mutations which enhance the replication of dengue virus type 4 and an antigenic chimeric dengue virus type ¾ vaccine candidate in Vero cells.'' *Vaccine.* 2003 Oct 1;21(27–30):4317–27 and Whitehead SS et al., ''A live, attenuated dengue virus type 1 vaccine candidate with a 30-nucleotide deletion in the 3' untranslated region is highly attenuated and immunogenic in monkeys.'' *J. Virol.* 2003 Jan;77(2):1653–7.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.

The field of use may be limited to live attenuated vaccines against dengue infections in humans.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 15, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–17318 Filed 7–18–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2013 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of intent to award a Single Source Grant to the current grantee of the Suicide Prevention Resource Center program.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award a programmatic supplement of approximately $583,330 (total costs) for up to one year to the current grantee of the Suicide Prevention Resource Center program. The current grantee is Education Development Center, Inc., Waltham, Massachusetts. This is not a formal request for applications. Assistance will be provided only to the Education Development Center, Inc. based on receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SM–13–008.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 520A and 520C of the Public Health Service Act, as amended.

Justification: The purpose of this 1-year supplement is to support implementation of the National Strategy for Suicide Prevention (NSSP) and to support the infrastructure of the National Action Alliance (Action Alliance) for Suicide Prevention, with the overall goal of reducing suicides and suicidal behaviors in the country.

Funds will be used to support implementation of the Action Alliance high priority area, to transform health care systems to significantly reduce suicide and suicide attempts.

This will also build on the momentum of the 2011 report released by the Action Alliance's Clinical Care and Intervention Task Force, *Suicide Care in Systems Framework,* including the informal ''zero suicide'' learning collaborative, which currently involves six states and health care systems.

Funds will also be used to directly support the infrastructure of the Action Alliance such as funding staff support for key Alliance initiatives, including the Action Alliance Executive Committee and task forces, and for direct meeting expenses of the Executive Committee and select task forces.

SAMHSA funds only one Suicide Prevention Resource Center, SAMHSA's primary vehicle for providing technical assistance to the field. Therefore, this program supplement will be awarded to the grantee that manages the SPRC, specifically to the Education Development Center, Inc., Waltham, Massachusetts. There are no other sources with the available resources and expertise to successfully complete the tasks of this proposal within the one-year grant period.

Contact: Cathy Friedman, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8–1097, Rockville, MD 20857; Telephone: (240) 276–2316; Email: *cathy.friedman@samhsa.hhs.gov.*

Cathy J. Friedman,

Public Health Analyst, SAMHSA.

[FR Doc. 2013–17276 Filed 7–18–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2013 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of intent to award a Single Source Grant to Link2Health Solutions, Inc.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately $200,000 (total costs) for up to one year to Link2Health Solutions, Inc. the current grantee for the National Suicide Prevention Lifeline. This is not a formal request for applications. Assistance will be provided only to Link2Health Solutions, Inc based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SM–13–012.

Catalog Of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 520A of the Public Health Service Act, as amended.

Justification: Only an application from Link2Health Solutions will be considered for funding under this announcement. It is considered most cost-effective and efficient to supplement the existing grantee for the National Suicide Prevention Lifeline and to build on the existing capacity and infrastructure.

Link2Health Solutions is in the unique position to carry out the activities of this grant announcement because it is the current recipient of SAMHSA's cooperative agreement to manage the National Suicide Prevention Lifeline. The purpose of this program is to manage, enhance, and strengthen the National Suicide Prevention Lifeline (referred to as the Lifeline). Supplemental funding is being provided for the National Suicide Prevention Lifeline as a result of increased need for services through non-traditional telephonic means (e.g. chat and text-based intervention services). Priorities and awareness raising activities will also be directed towards ensuring that the prevention needs of diverse populations will be addressed.

Contact: Cathy Friedman, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8–1097, Rockville, MD 20857; Telephone: (240) 276–2316; Email: *cathy.friedman@samhsa.hhs.gov.*

Cathy J. Friedman,

Public Health Analyst, SAMHSA.

[FR Doc. 2013–17269 Filed 7–18–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2013–0027]

Advisory Committee on Commercial Operations of Customs and Border Protection (COAC)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Advisory Committee on Commercial Operations of Customs and Border Protection (COAC) will meet on August 7, 2013, in Washington, DC. The meeting will be open to the public.

DATES: COAC will meet on Wednesday, August 7, from 1:00 p.m. to 5:00 p.m. e.s.t. Please note that the meeting may

close early if the committee has completed its business.

Pre-Registration: Meeting participants may attend either in person or via webinar after pre-registering using a method indicated below:

—For members of the public who plan to attend the meeting in person, please register either online at *https://apps.cbp.gov/te_reg/index.asp?w=7;* by email to *tradeevents@dhs.gov;* or by fax to 202–325–4290 by 5:00 p.m. EST on August 6, 2013.

—For members of the public who plan to participate via webinar, please register online at *https://apps.cbp.gov/te_reg/index.asp?w=8* by 5:00 p.m. EST on August 6, 2013.

Feel free to share this information with other interested members of the organization or association.

Members of the public who are pre-registered and later require cancellation, please do so in advance of the meeting by accessing one (1) of the following links: *https://apps.cbp.gov/te_reg/cancel.asp?w=7* to cancel an in person registration, or *https://apps.cbp.gov/te_reg/cancel.asp?w=8* to cancel a webinar registration.

ADDRESSES: The meeting will be held at the U.S. International Trade Commission (USITC) in Main Hearing Room 101, 500 E Street SW., Washington, DC 20436. All visitors to the USITC Building must show a state-issued ID or Passport to proceed through the security checkpoint for admittance to the building.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection at 202–344–1661 as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the committee prior to the formulation of recommendations as listed in the ''Agenda'' section below.

Comments must be submitted in writing no later than July 31, 2013, and must be identified by Docket No. USCBP–2013–0027, and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: Tradeevents@dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* 202–325–4290.
- *Mail:* Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Room 3.5A, Washington, DC 20229.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. Do not submit personal information to this docket.

Docket: For access to the docket to read background documents or comments received by the COAC, go to *http://www.regulations.gov.*

There will be three public comment periods held during the meeting on August 7, 2013. Speakers are requested to limit their comments to two (2) minutes or less to facilitate greater participation. Contact the individual listed below to register as a speaker. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP Web page, *http://www.cbp.gov/xp/cgov/trade/trade_outreach/coac/coac_13_meetings/,* at the time of the meeting.

FOR FURTHER INFORMATION CONTACT: Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Room 3.5A, Washington, DC 20229; telephone 202–344–1440; facsimile 202–325–4290.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 U.S.C. App. (Pub. L. 92–463). The COAC provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within DHS and the Department of the Treasury.

Agenda

The COAC will hear from the following project leaders and subcommittees on the topics listed below and then will review, deliberate, provide observations, and formulate recommendations on how to proceed on those topics:

1. COAC Survey Team: Review and Discuss Preliminary Results of the COAC 2013 Annual Trade Efficiency Survey and discuss feedback on past COAC recommendations.

2. The Export Subcommittee: Review and discuss subcommittee recommendations and the analysis of the 2013 COAC Export Survey Results.

3. The Trade Enforcement and Revenue Collection Subcommittee: Review and discuss the work completed to date on the Regulatory Audit Working Group's findings on the planned enhancements for the Focused Assessment process and the Intellectual Property Rights Working Group's effort to further evaluate the use of the Global Shipment Identification Number (GSIN) as a possible tool for use in Distribution Chain Management in Intellectual Property Rights Compliance.

4. The One U.S. Government at the Border Subcommittee: Review and discuss recommendations from the Food and Drug Administration (FDA) Working Group, review and discuss an update on the progress of the Environmental Protection Agency (EPA) Working Group, and review and discuss a case study regarding the Partner Government Agency—Message Set (PGA–MS).

5. The Trusted Trader Subcommittee: Review and discuss the work completed by the Industry Standards Working Group (ISWG) and the Trusted Trader Measures Working Group.

6. The Global Supply Chain Subcommittee: Review and discuss recommendations regarding the Air Cargo Advance Screening (ACAS) pilot and address the next steps regarding land border issues in the area of Beyond the Border and 21st Century Initiatives.

7. The Trade Modernization Subcommittee: Review and discuss recommendations addressing the Automated Commercial Environment (ACE) Development and Deployment Schedule and recommendations of the Role of the Broker Work Group.

Dated: July 16, 2013.

Maria Luisa Boyce,

Senior Advisor for Private Sector Engagement, Office of Trade Relations.

[FR Doc. 2013–17364 Filed 7–18–13; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5681–N–29]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh

Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Office of Enterprise Support Programs, Program Support Center, HHS, room 12–07, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Air Force:* Mr. Robert Moore, Air Force Real Property Agency, 2261 Hughes Avenue, Suite 156, Lackland AFB, TX, 78236–9852, (210)–395–9512; *Army:* Ms. Veronica Rines, Office of the Assistant Chief of Staff for Installation Management, Department of Army, Room 5A128, 600 Army Pentagon, Washington, DC 20310, (571)–256–814; *GSA:* Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501–0084; (These are not toll-free numbers).

Dated: July 11, 2013.

Mark Johnston,

Deputy Assistant Secretary for Special Needs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 07/19/2013

SUITABLE/AVAILABLE PROPERTIES

BUILDING

SOUTH CAROLINA

Building 1036
311 Avocet Street, Street, Shaw AFB
Sumter SC 29152
Landholding Agency: Air Force
Property Number: 18201320086
Status: Unutilized
Comments: off-site removal only; no future agency need; 1,694 sf.; open storage for auto hobby shop; repairs needed; secured area; contact AF for more info.

SUITABLE/AVAILABLE PROPERTIES

BUILDING

SOUTH CAROLINA

Building 1826
100 Shaw Dr., Shaw AFB
Sumter SC 29152
Landholding Agency: Air Force
Property Number: 18201320087
Status: Unutilized
Comments: off-site removal only; no future agency need; 984sf. washrack; repairs needed; secured area; contact AF for more info.

SUITABLE/UNAVAILABLE PROPERTIES

BUILDING

WASHINGTON

Recreational cabin; Lot 92
435 S. Shore Rd.
Quinault WA 98575
Landholding Agency: GSA
Property Number: 54201320018
Status: Excess
GSA Number: 9–A–WA–1267
Directions: Disposal Agency: GSA; Landholding Agency: Interior (US Forest Service)
Comments:
CORRECTION: Property is not available; unavailable because of conveyance restriction to family and individuals recreational use only; 524 sf.; remote location; vacant for 48 months; significant reconstruction to the cabin & infrastructure required for habitability; to be used for recreational purposes only; cannot be used as a residence; use restricted and subject to qualification for term Special Use Permit; contact GSA for more info.

UNSUITABLE PROPERTIES

BUILDING

CALIFORNIA

Building 305, 308, 205, 408, 208
700 E. Roth Rd.
Lathrop CA 95231
Landholding Agency: Army
Property Number: 21201330001
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising nat'l security

Reasons: Secured Area
Redding Outer
Adjacent Robinson Glen Dr. & Ges Pt. Rd.
Cottonwood CA 96002
Landholding Agency: GSA
Property Number: 54201320026
Status: Excess
GSA Number: 9–CA–1692
Directions: Disposal: GSA; Landholding Agency: Dept. of Transportation, FAA
Comments: landlocked; can only be reached by crossing private property & there is no established right or means of entry
Reasons: Not accessible by road

[FR Doc. 2013–17161 Filed 7–18–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZP02000.L51010000.ER0000. LVRWA12A2350.XXX; AZA–34177]

Notice of Availability of the Draft Environmental Impact Statement for the Sonoran Valley Parkway, Maricopa County, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), the Bureau of Land Management (BLM) has prepared a Draft Environmental Impact Statement (EIS) for the proposed Sonoran Valley Parkway Project (Parkway) and by this notice is announcing the opening of the comment period.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the Draft EIS for the Parkway within 45 days following the date the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**. The BLM will announce future meetings and any other public involvement activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: You may submit comments related to the proposed Parkway by any of the following methods:

- *Web site: http://www.blm.gov/az/st/en/prog/lands_realty/svpp-eis.html.*
- *Email: BLM_AZ_SVPP@blm.gov.*
- *Fax:* 623–580–5500.
- *Mail:* BLM Phoenix District Office, Lower Sonoran Field Office, Attention: Kathleen Depukat, Project Manager/Sonoran Valley Parkway, 21605 North 7th Avenue, Phoenix, AZ 85027–2929.

Copies of the Draft EIS for the proposed Parkway are available in the Phoenix District Office at the above address; the BLM Arizona State Office, One North Central Avenue, Suite 800, Phoenix, AZ 85004; and public library branches in Goodyear, Maricopa, and Avondale, Arizona, as noted in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kathleen Depukat, BLM Phoenix District Project Manager; telephone 623–580–5681; address 21605 North 7th Avenue, Phoenix, AZ 85027–2929; email *kdepukat@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The City of Goodyear submitted an application for a permanent 250-foot wide right-of-way (ROW) to the BLM for the construction and operation of a two to six-lane, approximately 15- to 18-mile-long Parkway. The proposed Parkway would connect residents of the annexed lands of Goodyear's Sonoran Valley Planning Area to the Goodyear, Arizona city center, Maricopa County, Arizona. The total length of the proposed Parkway depends on the Alternative and/or Sub-alternative selected and authorized by the BLM. The Parkway is proposed to be built in three phases of two lanes each. The timeframe for the phased construction will be determined based on current and future growth in the area. The first phase of the proposed Parkway will be built as soon as funding can be obtained by the City of Goodyear.

The majority of the proposed Parkway would be located on the BLM lands administered by the Lower Sonoran Field Office; the remainder would occur on private and Arizona State Land Department lands. The BLM-managed lands within the proposed Parkway area are managed under the Lower Sonoran Resource Management Plan. The proposed Parkway would commence at the intersection of Rainbow Valley Road and Riggs Road and run in a southeasterly direction, within the eastern and northern portion of the existing El Paso Natural Gas designated multi-use utility corridor, to State Route (SR) 238 at a point just west of the community of Mobile, Arizona.

The BLM's purpose and need for this action is to respond to Goodyear's application under Title V of the Federal Land Policy and Management Act of 1976 (FLPMA) (43 USC 1761 *et seq.*), for a ROW grant to construct, operate, and maintain a proposed two- to six-lane Parkway in compliance with FLPMA, the BLM ROW regulations, and other applicable Federal laws. The BLM will decide whether to approve, approve with modification, or deny the issuance of a ROW grant to Goodyear for the proposed Parkway.

The BLM published a Notice of Intent (NOI) to prepare an EIS on April 2, 2008, in the Federal Register (73 FR 17995). Publication of the NOI began a 30-day scoping period, which ended on May 1, 2008. The BLM provided a Web site with project information that also described the various methods of providing public comment on the project, including an email address for the BLM to receive scoping comments electronically. Notifications for public scoping meetings were posted on the BLM's Web site. Additionally, notices were announced in the **Federal Register** on April 2, 2008, and published in a legal ad in the City of Goodyear's *InFocus* Newsletter in May 2008; postcards were mailed to the BLM stakeholder list on May 7–9, 2009.

Public Scoping Meetings were held on May 28, 2009, at the Goodyear City Hall and on May 29, 2008, at the Global Water Conference Center in Maricopa and the Mobile Elementary School in Mobile, Arizona. Attendees were documented using a voluntary sign-in sheet showing 7 attendees at the City of Goodyear, 9 attendees at the Global Water Conference Center, and 16 attendees at the Mobile Elementary School. A contractor documented the questions and public comments made at the three scoping meetings. Attendees included residents from Phoenix, Maricopa, Mobile, and Goodyear, Federal and State agency representatives, tribes, and a public citizens' group.

Seventeen comment letters or emails were received within the scoping period. The issues addressed in the Draft EIS that shaped the Parkway's scope and proposed alternatives include air resources, cultural and heritage resources, paleontological resources, soil resources, vegetation resources, visual resources, water resources, wildland fire management, wildlife and special status species, lands and realty, livestock grazing, recreation management, travel management, special designations, noise, hazardous materials and public safety, and social and economic conditions.

In addition to the Proposed Action (Alternative A) and No Action Alternative, the Draft EIS for the Parkway considers two proposed Action Alternatives and two proposed Action Sub-alternative routes that were

analyzed in detail in the Draft EIS. The Sub-alternatives were developed to avoid a historic homestead site near the southern terminus of the proposed alignment in Mobile at SR 238. The Alternative A is within an existing one-mile-wide multi-use utility corridor that borders the Sonoran Desert National Monument. The entire Alternative A is within Class IV for Visual Resource Management. The project area is within known habitat for the Sonoran Desert tortoise and the Tucson shovel-nosed snake. There are also two designated wildlife movement corridors. The first corridor is the Sierra Estrella-Sonoran Desert National Monument linkage for bobcat, desert tortoise, Gila monster, javelina, and mule deer as designated in the Arizona Wildlife Linkages Assessment. The second corridor is the BLM-designated wildlife corridor adopted from the Arizona Game and Fish Department Bighorn Sheep Management Plan and present within the proposed Parkway area for all alternatives. All Sub-alternatives for the southern terminus will cross the congressionally designated Juan Bautista de Anza National Historic Trail, the Butterfield Overland Stage Trail, and the Mormon Battalion Trail which are located within the Lower Gila Terraces and Historic Trails Area of Critical Environmental Concern. However, the locations where the proposed Parkway Sub-alternatives would cross the three trails are located on private land not managed by the BLM. The EIS does include suggested mitigation measures that would address the impacts to the Juan Bautista de Anza National Historic Trail, the Butterfield Overland State Trail, and the Mormon Battalion Trail on private land. An interdisciplinary approach was used to develop the Draft EIS in order to consider the variety of resource issues and concerns identified. A modified Proposed Action, Alternative A, including Sub-alternative G is the BLM's preferred alternative. The BLM will utilize and coordinate the NEPA comment period to satisfy the public involvement process for Section 106 of the National Historic Preservation Act (16 U.S.C. 470), as provided for in 36 CFR 800.2(d)(3). Native American tribal consultations are being conducted in accordance with policy, and tribal concerns, including impacts on Indian trust assets, will be given due consideration. Federal, State, and local agencies, along with other stakeholders that may be interested or affected by the BLM's decision on this project, are invited to participate in the public comment process. Please note that public comments and information submitted, including names, street addresses, and email addresses of persons who submit comments, may be available for public review and disclosure at the above address during regular business hours (8 a.m. to 4 p.m.), Monday through Friday, except holidays.

Copies of the Draft EIS for the proposed Parkway are available in the BLM Arizona State Office, One North Central Avenue, Suite 800, Phoenix, AZ 85004; the Phoenix District Office at the above address; the Goodyear Branch Library, 250 North Litchfield Road, Suite 185, Goodyear, AZ 85338; the Maricopa Public Library, 41600 W. Smith-Enke Road, Building #10, Maricopa, AZ 85138; the Old Town Branch Library, 328 West Western Avenue, Avondale, AZ 85323; and the Avondale City Library, 495 East Western Avenue, Avondale, AZ 85323.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10.

Dorothea J. Boothe,

Acting, Lower Sonoran Field Manager.

[FR Doc. 2013–17265 Filed 7–18–13; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[L51010000.FX0000.LVRWA11A2990. LLAZP02000.XXX; AZA35079]

Notice of Availability of the Final Environmental Impact Statement for the Proposed Sun Valley to Morgan Transmission Line Project (Formerly Called TS–5 to TS–9) and the Proposed Bradshaw-Harquahala Resource Management Plan Amendment, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) has prepared a Final Environmental Impact Statement (EIS) for the proposed Sun Valley to Morgan 500/230-kilovolt (kV) Transmission Line Project (Project) and Proposed Bradshaw-Harquahala Resource Management Plan (RMP) Amendment for the BLM Hassayampa Field Office, and by this notice is announcing its availability.

DATES: BLM planning regulations state that any person who meets the conditions as described in the regulations may protest the BLM's Proposed RMP Amendment/Final EIS. A person who meets the conditions must file the protest within 30 days of the date that the Environmental Protection Agency publishes its notice in the **Federal Register**.

ADDRESSES: Copies of the Final EIS and Proposed RMP Amendment have been sent to affected Federal, State, and local government agencies and to other stakeholders. Copies of the Final EIS/Proposed RMP Amendment are available for public inspection at local libraries and the BLM Hassayampa Field Office.

Interested persons may also review the Final EIS/Proposed RMP Amendment on the Internet at *http://www.blm.gov/az/st/en/prog/energy/aps-sunvalley.html.* All protests must be in writing and mailed to one of the following addresses:

Regular Mail: BLM Director (210), Attention: Brenda Hudgens-Williams, P.O. Box 71383, Washington, DC 20024.

Overnight Mail: BLM Director (210), Attention: Brenda Hudgens-Williams, 20 M Street SE., Room 2134 LM, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Joe Incardine, BLM National Project Manager, telephone 801–539–4118; address BLM Phoenix District Office, Hassayampa Field Office, 21605 North 7th Avenue, Phoenix, AZ 85027–2929; email *jincardi@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Arizona Public Service Company (APS) submitted a right-of-way (ROW) application to construct, operate, and maintain a 500/230-kV overhead transmission line from the Sun Valley Substation to the Morgan Substation in Maricopa County. The APS was reacting

to a decision in 2009 by the Arizona Corporation Commission, the line-siting authority in the State, to certificate a route that includes the BLM-managed lands.

The proposed Project would be located on a combination of BLM-managed lands, Arizona State Trust lands, and private lands in northern Maricopa County, northwest of Phoenix, Arizona. The proposed Project is an overhead transmission line, approximately 38 miles long, on monopole structures. The BLM-managed lands within the Project area are managed under the existing Bradshaw-Harquahala RMP.

Environmental and social concerns and issues were identified through both the initial public scoping and Draft EIS/Draft RMP Amendment comment periods. The issues addressed in the EIS that shaped the Project's scope and alternatives include:

- Land Use Plan conformance;
- Need and reliability;
- Project design features, mitigation measures, and alternatives;
- Air and climate;
- Biological resources;
- Cultural resources;
- Health and safety;
- Recreation;
- Socioeconomic and environmental justice;
- Scenic/Visual; and
- Transportation and traffic.

In addition to the Proposed Action and No Action Alternative, three action alternative routes and one sub-alternative route (as proposed by the Arizona State Land Department) were analyzed in detail in the EIS. As proposed, the Project would require an RMP Amendment because the current RMP requires high-voltage transmission lines crossing BLM-managed lands to be within designated utility corridors, and a utility corridor for the proposed ROW was not established in the current RMP. However, the Proposed Action is within a transportation corridor which is designated for the expansion of State Route 74. In addition, the Visual Resource Management (VRM) class designation would need to be amended from Class III to Class IV for those BLM-managed lands where views would be dominated by the transmission line and thus would not meet the objectives of the current VRM designation. The VRM class would also be changed for those BLM-managed lands south of State Route (SR) 74 surrounding the proposed transmission line ROW (i.e., the existing transportation corridor north of SR 74 and the key-shaped piece south of SR 74).

An interdisciplinary approach was used to develop the Final EIS in order to consider the variety of resource issues and concerns identified. An amendment to the Bradshaw-Harquahala RMP would be based upon the following planning criteria:

- The amendment would be completed in compliance with FLPMA, NEPA, and all other relevant Federal laws, executive orders, and management policies of the BLM;
- Where existing planning decisions are still valid, those decisions would remain unchanged and be incorporated into the new amendment; and
- The amendment would recognize valid existing rights.

The BLM has identified the Proposed Action route (with slight modifications as needed to reduce potential impacts) crossing BLM-managed lands as the Agency Preferred Alternative route for the proposed transmission line, including best management practices (BMPs). The BMPs would consist of minor route deviations for micro-siting of structures or segments of the line at the time of route engineering to reduce impacts to visual and other sensitive resources.

Under the Agency Preferred Alternative, the BLM would amend the RMP to:

- Designate a 200-foot-wide utility corridor (2,362 acres) on BLM-managed lands north of SR 74, and eliminate Decision LR–30, which states that there would be no new utility corridors designated in the Castle Hot Springs Management Unit;
- Designate a multiuse utility corridor on 1,013 acres of BLM-managed lands south of SR 74 (key shaped area) to address potential future BLM management considerations; and
- Change the existing VRM class designations of 2,362 acres north of SR 74 and 1,013 acres south of SR 74 from VRM Class III to VRM Class IV to allow for the newly established utility corridors.

If the BLM approves the RMP Amendment, the BLM would also approve a ROW on BLM-managed lands.

The BLM has utilized the NEPA comment period to satisfy the public involvement process for Section 106 of the National Historic Preservation Act (16 U.S.C. 470) as provided for in 36 CFR 800.2(d)(3). Native American tribal consultations will continue to be conducted in accordance with policy, and tribal concerns, including impacts on Indian trust assets, will be given due consideration.

Comments on the Draft EIS/Draft RMP Amendment received from the public and internal BLM review were considered, and document revisions were incorporated as appropriate into the Final EIS/Proposed RMP Amendment. Public comments resulted in the addition of clarifying text, but did not result in significant changes to the proposed Project, the Proposed RMP Amendment, or the impact analysis between the Draft and Final EIS.

Instructions for filing a protest with the BLM Director regarding the Final EIS/Proposed RMP Amendment may be found in the ''Dear Reader'' Letter of the APS Sun Valley to Morgan Transmission Line Project Final EIS and Proposed RMP Amendment and at 43 CFR 1610.5–2. Emailed protests will not be accepted as valid protests unless the protesting party also provides the original letter by either regular or overnight mail postmarked by the close of the protest period. Under these conditions, the BLM will consider the emailed protest as an advance copy and it will receive full consideration. If you wish to provide the BLM with such advance notification, please direct email protests to the attention of the BLM protest coordinator Brenda Hudgens-Williams at *bhudgens@blm.gov.*

All protests must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section above.

Before including your phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2, 43 CFR 1610.5.

Raymond Suazo,

State Director.

[FR Doc. 2013–17226 Filed 7–18–13; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLUT980300–L11200000–PH0000–24–1A]

Utah Resource Advisory Council Meeting/Conference Call

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Meeting/Conference Call

SUMMARY: In accordance with the Federal Land Policy and Management

Act and the Federal Advisory Committee Act, the Bureau of Land Management's (BLM) Utah Resource Advisory Council (RAC) will host a meeting/conference call.

DATES: The Utah RAC will host a meeting/conference call on Wednesday, August 21, 2013, from 8:30 a.m.–12:30 p.m., MST.

ADDRESSES: Those attending in person must meet at the BLM, Utah State Office, 440 West 200 South, Salt Lake City, Utah, in the Monument Conference Room on the fifth floor.

FOR FURTHER INFORMATION CONTACT: If you wish to listen to the teleconference, orally present material during the teleconference, or submit written material for the RAC to consider during the teleconference, please notify Sherry Foot, Special Programs Coordinator, Bureau of Land Management, Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101; phone 801–539–4195; or, *sfoot@blm.gov* by Friday, August 16, 2013.

SUPPLEMENTARY INFORMATION: The Utah RAC formed a subgroup to review BLM-Utah's draft three-year National Conservation Lands Strategy. In June 2013, the RAC subgroup provided the BLM-Utah State Director with recommended changes to the draft strategy and this meeting will be held to discuss the changes. A public comment period will take place immediately following the presentation. The meeting is open to the public; however, transportation, lodging, and meals are the responsibility of the participating individuals. The conference call will be recorded for purposes of minute-taking.

Authority: 43 CFR 1784.4–1.

Jenna Whitlock,

Associate State Director.

[FR Doc. 2013–17356 Filed 7–18–13; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–IMR–GLAC–12985; PPIMGLAC00, PANFHAT44.YP0000]

Going-to-the-Sun Road Corridor Management Plan, Environmental Impact Statement, Glacier National Park, Montana

AGENCY: National Park Service, Interior.

ACTION: Notice of intent.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, the National Park Service is preparing an Environmental Impact Statement for the Going-to-the-Sun Road Corridor Management Plan for Glacier National Park, Montana. This effort will result in an integrated visitor and transportation management plan for the Going-to-the Sun Road (GTSR) corridor.

DATES: The National Park Service will accept comments from the public through August 19, 2013.

ADDRESSES: Information will be available for public review and comment online at *http://parkplanning.nps.gov/glac,* and at the Park's Information Desk at Headquarters in West Glacier Montana at (406) 888–7800.

FOR FURTHER INFORMATION CONTACT: Mary Riddle, Chief of Planning and Compliance, Glacier National Park, P.O. Box 128 West Glacier, Montana 59936; or via telephone at (406) 888–7898.

SUPPLEMENTARY INFORMATION: A range of alternatives including no action will be developed that address long term financial sustainability of the park's shuttle system, management of visitor use, and congestion and protection of natural and cultural resources in the GTSR corridor. The Plan will also explore management approaches that can be adapted to changing conditions, identify triggers or standards and indicators and develop monitoring system to assure protection of resources and continue to provide a quality visitor experience.

A scoping brochure and other materials describing the issues and overall purpose of the project will be prepared and distributed to the public including Tribes, federal, state local agencies and specific interest groups. Information may be obtained from the internet site: *http://parkplanning.nps.gov/glac,* and from the Park's Information Desk at Glacier National Park, Headquarters, P.O. Box 128, West Glacier, Montana 59936; or via telephone at (406) 888–7800.

If you wish to comment on the scoping brochure or on any other issues associated with the plan, you may submit your comments by any one of several methods. You may mail comments to Glacier National Park Attn: GTSR Corridor Plan P.O. Box 128 West Glacier, Montana 59936. You may also comment via the Internet at *http://parkplanning.nps.gov/glac.* Finally, you may hand-deliver comments to Glacier National Park Headquarters, West Glacier Montana. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: June 6, 2013.

Laura E. Joss,

Deputy Regional Director, Chief of Staff, Intermountain Region.

[FR Doc. 2013–17375 Filed 7–18–13; 8:45 am]

BILLING CODE 4312–CB–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1202–03 (Final)]

Xanthan Gum From Austria and China

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (Commission) determines, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act), that an industry in the United States is not materially injured or threatened with material injury by reason of imports from Austria of xanthan gum provided for in subheading 3913.90.20 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce (Commerce) to be sold in the United States at less than fair value.

The Commission also determines, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act), that an industry in the United States is threatened with material injury by reason of imports from China of xanthan gum provided for in subheading 3913.90.20 of the Harmonized Tariff Schedule of the United States, that have been found by Commerce to be sold in the United States at less than fair value.[2]

Background

The Commission instituted these investigations effective June 5, 2012, following receipt of a petition filed with the Commission and Commerce by CP Kelco U.S., Atlanta, Georgia. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioner Dean A. Pinkert and Commissioner Meredith M. Broadbent determine that an industry in the United States is materially injured by reason of imports from China of xanthan gum.

imports of xanthan gum from Austria and China were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of February 27, 2013 (78 FR 13379). The hearing was held in Washington, DC, on May 23, 2013, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on July 12, 2013. The views of the Commission are contained in USITC Publication 4411 (July 2013), entitled *Xanthan Gum From Austria and China: Investigation Nos. 1202–03 (Final).*

Issued: July 16, 2013.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–17344 Filed 7–18–13; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (BJA) Docket No. 1627]

Meeting of the Public Safety Officer Medal of Valor Review Board

AGENCY: Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA). DOJ.

ACTION: Notice of meeting.

SUMMARY: This is an announcement of a meeting of the Public Safety Officer Medal of Valor Review Board to review and vote on recommendations for the 2012–2013 Medal of Valor nominations, consider issues relevant to the nomination review process, discuss pending ceremonies and upcoming activities and other relevant Board issues related thereto. The meeting date and time is listed below.

DATES: September 19, 2013, 9:00 a.m. to 1:00 p.m. ET.

ADDRESSES: This meeting will take place at 810 7th Street NW., Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: Gregory Joy, Policy Advisor, Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street NW., Washington, DC 20531, by telephone at (202) 514–1369, toll free (866) 859–2687, or by email at *gregory.joy@usdoj.gov.*

SUPPLEMENTARY INFORMATION: The Public Safety Officer Medal of Valor Review Board carries out those advisory functions specified in 42 U.S.C. 15202. Pursuant to 42 U.S.C. 15201, the President of the United States is authorized to award the Public Safety Officer Medal of Valor, the highest national award for valor by a public safety officer.

The primary purpose of this meeting is to review and vote on recommendations for the 2012–2013 Medal of Valor nominations.

This meeting is open to the public at the offices of the Bureau of Justice Assistance. For security purposes, members of the public who wish to participate must register at least seven (7) days in advance of the meeting/conference call by contacting Mr. Joy. All interested participants will be required to meet at the Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street NW., Washington, DC and will be required to sign in at the front desk. Note: Photo identification will be required for admission. Additional identification documents may be required.

Access to the meeting will not be allowed without prior registration. Anyone requiring special accommodations should contact Mr. Joy at least seven (7) days in advance of the meeting. Please submit any comments or written statements for consideration by the Review Board in writing at least seven (7) days in advance of the meeting date.

Gregory Joy,

Policy Advisor/Designated Federal Officer, Bureau of Justice Assistance.

[FR Doc. 2013–17329 Filed 7–18–13; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection, Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed extension of the ''American Time Use Survey.'' A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the Addresses section of this notice on or before September 17, 2013.

ADDRESSES: Send comments to Amelia Vogel, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue NE., Washington, DC 20212. Written comments also may be transmitted by fax to 202–691–5111 (this is not a toll free number).

FOR FURTHER INFORMATION CONTACT: Amelia Vogel, BLS Clearance Officer, at 202–691–7628 (this is not a toll free number). (See Addresses section.)

SUPPLEMENTARY INFORMATION:

I. Background

The ATUS is the Nation's first federally administered, continuous survey on time use in the United States. It measures, for example, time spent with children, working, sleeping, or doing leisure activities. In the United States, several existing Federal surveys collect income and wage data for individuals and families, and analysts often use such measures of material prosperity as proxies for quality of life. Time-use data substantially augment these quality-of-life measures. The data also can be used in conjunction with wage data to evaluate the contribution of non-market work to national economies. This enables comparisons of production between nations that have different mixes of market and non-market activities.

The ATUS develops nationally representative estimates of how people spend their time. Respondents also report who was with them during activities, where they were, how long each activity lasted, and if they were paid. All of this information has numerous practical applications for sociologists, economists, educators,

government policymakers, businesspersons, health researchers, and others, potentially answering the following questions:

- Do the ways people use their time vary across demographic and labor force characteristics, such as age, sex, race, ethnicity, employment status, earnings, and education?
- How much time do parents spend in the company of their children, either actively providing care or being with them while socializing, relaxing, or doing other things?
- How are earnings related to leisure time—do those with higher earnings spend more or less time relaxing and socializing?
- Where do people work—at a workplace, in their homes, or someplace else?

The ATUS data are collected on an ongoing, monthly basis, allowing analysts to identify changes in how people spend their time.

II. Current Action

Office of Management and Budget clearance is being sought for the American Time Use Survey.

This survey collects information on how individuals in the United States use their time. Collection is done on a continuous basis with the sample drawn monthly. The survey sample is drawn from households completing their 8th month of interviews for the Current Population Survey (CPS). Households are selected to ensure a nationally-representative demographic sample, and one individual from each household is selected to take part in one Computer Assisted Telephone Interview. Interviewers ask respondents to report all of their activities for one pre-assigned 24-hour day, the day prior to the interview. A short series of summary questions and CPS updates follows the core time diary collection. After each full year of collection, annual national estimates of time use for an average day, weekday, and weekend day are available.

Because the ATUS sample is a subset of households completing interviews for the CPS, the same demographic information collected from that survey is available for ATUS respondents. Comparisons of activity patterns across characteristics such as sex, race, age, disability status, and education of the respondent, as well as the presence of children and the number of adults living in the respondent's household, are possible.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Type of Review: Extension without change of a currently approved collection.

Agency: Bureau of Labor Statistics.

Title: American Time Use Survey.

OMB Number: 1220–0175.

Affected Public: Individuals or households.

Total Respondents: 13,200.

Frequency: Once.

Total Responses: 13,200.

Average Time per Response: 16 minutes.

Estimated Total Burden Hours: 3,520 hours.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC, this 12th day of July 2013.

Kimberley D. Hill,

Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2013–17351 Filed 7–18–13; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, With Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA is submitting the following information collection to the Office of Management and Budget (OMB) for reinstatement under the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. Chapter 35). Notice of this information collection is published to obtain comments from the public. Under the Home Mortgage Disclosure Act (HMDA), financial institutions that meet the reporting criteria must compile and make available data about their housing-related lending activity. The data is made available to the public for the purposes of: (i) Helping to determine whether financial institutions are serving the housing needs of their communities; (ii) assisting public officials in distributing public-sector investment so as to attract private investment to areas where it is needed; and (iii) assisting in identifying possible discriminatory lending patterns and enforcing anti-discrimination statutes. The information collection will assist NCUA to ensure credit unions are in compliance with fair lending laws and regulations.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA contact and OMB reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Contact: ATTN: Desk Officer for the National Credit Union Administration, Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION: Proposal for the following collection of information:

I. Abstract and Request for Comments

NCUA is reinstating the information collection previously approved under OMB control number 3133–0166. Under HMDA, depository institutions that have a home office or branch office located within a metropolitan statistical area must compile and make available to the public the number and total dollar amount of mortgage loans originated (or for which the institution received completed applications) or purchased during each year. 12 U.S.C. 2801 et seq. The Consumer Financial Protection Bureau implements HMDA under Regulation C, 12 CFR Part 1003. Regulation C requires financial institutions and mortgage lending institutions to report data about home purchase loans and refinancings that originated or purchased, or for which applications were received, and to disclose the data to the public.

Under this information collection, credit unions meeting the criteria described in HMDA and Regulation C must compile, report, and make available data about home purchase loans and refinancings they originate, purchase, or for which they receive applications. The data is made available to the public to help to determine whether credit unions, along with other financial institutions and other mortgage lenders, are serving the housing needs of their members and to assist public officials in distributing public-sector investment so as to attract private investment to areas where it is needed. Additionally, federal regulators use the data to identify possible discriminatory lending patterns and enforce antidiscrimination statutes.

Specifically, NCUA uses HMDA data to examine credit union compliance with the Equal Credit Opportunity Act and the Fair Housing Act. NCUA also uses the data to report credit union lending practices to Congress and the public. The Federal Financial Institutions Examination Council compiles the data and makes it available to the public annually to carry out the purposes of HMDA.

NCUA is requesting reinstatement of OMB control number 3133–0166, with changes in the estimated burden due to an increase in the number of reporting credit unions and the cost of the technology used to submit the information. Since the initial approval of the information collection, the number of credit unions involved in mortgage lending has increased slightly from 1,996 credit unions to 2,015 credit unions. The estimated cost of the information collection has been adjusted to reflect the cost of programmatic modifications associated with increased number of respondents and the use of technology. The increase in the number of respondents caused a corresponding increase in the estimated burden hours associated with the collection, even though NCUA estimates the time per reportable loan application necessary to submit the information collection will not change.

NCUA requests that you send your comments on this collection to the location listed in the **ADDRESSES** section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: HMDA Requirements under 12 U.S.C. 2801–2810 and Regulation C, 12 CFR Part 1003.

OMB Number: 3133–0166.

Form Number: None.

Type of Review: Reinstatement, with change, of a previously approved collection.

Description: The collection of this data is required under the Home Mortgage Disclosure Act. The data collection is intended to provide the public with loan data that can be used (1) To help determine whether financial institutions are serving the housing needs of their communities; (2) to assist public officials in distributing public-sector investments so as to attract private investment to areas where it is needed; and (3) to assist in identifying possible discriminatory lending patterns and enforcing anti-discrimination statutes.

Respondents: Credit unions.

Estimated No. of Respondents/Record keepers: 2,015.

Estimated Burden Hours per Response: 47.25 hours.

Frequency of Response: Record-keeping, Third party disclosure and Reporting Annually.

Estimated Total Annual Burden Hours: 95,210 hours.

Estimated Total Annual Cost: $1,428,150.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17346 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, With Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). This information collection is published to obtain comments from the public. Part 749 of the NCUA Regulations directs each credit union to have a vital records preservation program that includes procedures for maintaining duplicate vital records at a location far enough from the credit union's offices to avoid the simultaneous loss of both sets of records in the event of a disaster. Part 749 requires a written vital records preservation program that includes a schedule for the storage and destruction of records and emergency contact information for employees, officials, regulatory offices, and vendors used to support vital records.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted

comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and request for comments

NCUA is reinstating and amending the collection for 3133–0032. Credit union records preservation programs enable NCUA to ensure that federally-insured credit unions (FICUs) can reconstruct their vital records in the event that records are destroyed by a catastrophe and facilitates restoration of vital member services. The program does not have to be submitted to the NCUA but must be available for review by examination staff. The frequency of collection will be unique to each credit union based on its operations, storage schedule, and storage methods, but occurs on a flow basis at least quarterly. NCUA has modified the cost basis for this data collection to focus on the recordkeeping labor cost of maintaining a records preservation program rather than the technology cost to store records offsite. NCUA believes that electronically backing up and storing credit union records offsite has become a usual and customary business practice. Therefore, credit union labor costs are the appropriate recordkeeping burden associated with maintaining a records preservation program under Part 749. This is the primary reason why the total annual burden has decreased, along with a decline in the number of FICUs from 8,420 to 6,753 and newly chartered FICUs from 15 to 5.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: Records Preservation under 12 CFR Part 749.

OMB Number: 3133–0032.

Form Number: None.

Type of Review: Reinstatement, with change, of a previously approved collection.

Description: Part 749 of NCUA Regulations directs each credit union to develop and maintain a records preservation program and maintain a log for records stored and destroyed.

Respondents: All credit unions.

Estimated No. of Respondents/Recordkeepers: 6,758. This total consists of 6,753 existing FICUs as of 3/31/2013, and an anticipated 5 newly chartered FICUs in 2013.

Estimated Burden Hours Per Response: 2 hours for existing FICUs and 8 hours for newly chartered FICUs.

Frequency of Response: Quarterly.

Estimated Total Annual Burden Hours: 13,546

Estimated Total Annual Cost: $427,512

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17337 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, Without Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). This information collection is published to obtain comments from the public. NCUA is renewing the requirements for Federally Insured Credit Unions to maintain an information security program and an incident response plan that complies with Title V of the Gramm-Leach-Bliley Act, 15 U.S.C. 6801 et seq. The program and response plan are required by Part 748 of the NCUA Rules and Regulations. Appendix B contains guidance on creating an effective incident response plan in the event of unauthorized access to member information and the requirements of the notices distributed to the affected members.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov*.

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is amending/reinstating the collection for 3133–0033. NCUA is renewing the requirements for Federally Insured Credit Unions to maintain an information security program and an incident response plan that complies with Title V of the Gramm-Leach-Bliley Act, 15 U.S.C. 6801 et seq. Section 748.0 of NCUA's regulations, 12 CFR 748.0, directs federally insured credit unions to adopt a security program that includes ensuring the security and confidentiality of member records, protecting against the anticipated threats or hazards to the security or integrity of such records, and protecting against unauthorized access to or use of such records that could result in substantial harm or serious inconvenience to a member. The security program also contains a requirement to respond to incidents of unauthorized access to or use of member information that could result in substantial harm or serious inconvenience to a member. Proper incident response includes a notification requirement to the affected member. NCUA examiners review the programs to determine whether the credit union's procedures comply with the information security and incident response requirements. There is a decrease of 39,776 hours from the last submission (2007). The decrease is a result of an adjustment to the number of credit unions from 8,695 to 6,753. This decline is from credit union mergers and liquidations.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section.

Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: 12 CFR Part 748, Security Program and Appendix B.

OMB Number: 3133–0033.

Form Number: None.

Type of Review: Third party disclosure, and reporting, on occasion.

Description: 12 CFR Part 748 requires federally insured credit unions to develop a written security program to safeguard sensitive member information. This information collection requires that such programs be designed to respond to incidents of unauthorized access or use, in order to prevent substantial harm or serious inconvenience to members.

Respondents: Federally insured credit unions.

Estimated No. of Respondents/Record keepers: 6,753.

Estimated Burden Hours per Response: 20 hours.

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 138,300 hours.

Estimated Total Annual Cost: None.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17353 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, Without Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). This information collection is published to obtain comments from the public. Section 701.32 of the NCUA Rules and Regulations (12 CFR 701) limits nonmember and public unit deposits in federally insured credit unions to 20 percent of their shares or $3.0 million, whichever is greater.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is reinstating the collection for 3133–0114. The collection of information requirement is that those credit unions seeking an exemption from the nonmember deposit limit must adopt a specific written plan and submit their lending and investment policies, a copy of their latest financial statement, and an explanation of the request to the NCUA Regional Director. NCUA uses this information to determine whether a particular credit union will be granted an exemption to the limit on nonmember and public unit deposits. This collection of information is necessary to protect the National Credit Union Share Insurance Fund (''Fund''). There is no change to the burden hours from previous submissions.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: Payment on Shares by Public Units and Nonmembers.

OMB Number: 3133–0114.

Form Number: None.

Type of Review: Reinstatement, without change, of a previously approved collection.

Description: 5 CFR 701.32 limits nonmember and public unit deposits in federally insured credit unions to 20 percent of their shares or $3.0 million, whichever is greater. The collection of information requirement is for those credit unions seeking an exemption from the above limit.

Respondents: Credit Unions seeking an exemption from the limits on share deposits by public unit and nonmember accounts set by 5 CFR 701.32.

Estimated No. of Respondents/Recordkeepers: 20.

Estimated Burden Hours per Response: 2 hours.

Frequency of Response: Other. As exemption is requested.

Estimated Total Annual Burden Hours: 40.

Estimated Total Annual Cost: $1,240.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17340 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, Without Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995

(Pub. L. 104–13, 44 U.S.C. Chapter 35). This information collection relates to 12 CFR part 713 which requires a federal credit union (FCU) to monitor its eligibility to qualify for a higher fidelity coverage deductible and to notify the NCUA if its financial condition changes resulting in the loss of that eligibility for the higher deductible. This information collection notice is published to obtain comments from the public. This requirement enables NCUA to monitor the FCU's financial condition for safety and soundness purposes and helps to assure that FCUs are properly and adequately protected against potential losses due to insider abuse such as fraud and embezzlement.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is reinstating a previously approved collection of information for 3133–0170. The regulation calls for an FCU that ceases to meet eligibility requirements for the higher deductible to obtain a policy with the required coverage and to notify the appropriate NCUA regional office of its changed status. The notice must also confirm that the FCU has obtained the required coverage. The information will be used by the regional office in its efforts to monitor credit unions for safe and sound operations and is critically important in helping to avert or minimize losses to the National Credit Union Share Insurance Fund (NCUSIF). The NCUSIF provides federally guaranteed account insurance for all federally insured credit unions. Adequate insurance coverage can avert a credit union from failing due to insolvency; alternatively, where insolvency and failure do occur, the NCUA, in its capacity as receiver for the failed FCU, can recoup some of its losses through a claim under an insurance policy.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: 12 CFR part 713, Fidelity Bond and Insurance Coverage for Federal Credit Unions.

OMB Number: 3133–0170.

Form Number: None.

Type of Review: Reinstatement, without change, of a previously approved collection.

Description: The regulation in 12 CFR part 713, details the requirements for FCU compliance regarding fidelity bond and insurance coverage. The regulation includes instructions for those FCUs that no longer qualify for a higher deductible.

Respondents: Federal credit unions.

Estimated No. of Respondents/Recordkeepers: 5.

Estimated Burden Hours per Response: 1 hour.

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 5 hours.

Estimated Total Annual Cost: None.

By the National Credit Union Administration Board, on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17347 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, With Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). The information collection relates to requests for non-public records and for testimony by NCUA employees in legal proceedings. This information collection notice is published to obtain comments from the public.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is reinstating a previously approved collection of information for 3133–0146. 12 CFR Part 792, Subpart C requires anyone requesting NCUA non-public records for use in legal proceedings, or similarly the testimony of NCUA personnel, to provide NCUA with information regarding the requester's grounds for the request. This process is also known as a ''Touhy Request''. The information collected will help the NCUA decide whether to release non-public records or permit employees to testify in legal proceedings.

NCUA regulations also require an entity or person in possession of NCUA records to notify the NCUA upon receipt of a subpoena for those records. The NCUA requires this notice to protect its records and, when necessary, intervene in litigation or file an objection to the disclosure of its confidential information in the appropriate court or tribunal.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: Production of Non-public Records and Testimony of Employees in Legal Proceedings (Touhy Request).

OMB Number: 3133–0146.

Form Number: None.

Type of Review: Reinstatement, with change, of a previously approved collection.

Description: The regulation in 12 CFR Part 792, Subpart C details the requirements for obtaining the production of nonpublic NCUA records for use in legal proceedings and testimony of NCUA personnel.

Respondents: Respondents will most likely be persons involved in legal proceedings.

Estimated No. of Respondents/ Recordkeepers: 20

Estimated Burden Hours per Response: 2 hours.

Frequency of Response: Reporting, on occasion.

Estimated Total Annual Burden Hours: 40.

Estimated Total Annual Cost: None.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17341 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement of a Previously Approved Information Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). This information collection is published to obtain comments from the public.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov*.

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is reinstating the collection for 3133–0108. Section 748.2 of NCUA's regulations, 12 CFR 748.2, directs credit unions to adopt a written program and to maintain procedures that ensure the credit union's continued compliance with the Bank Secrecy Act (BSA) (31 U.S.C. 5311–5330) and Department of Treasury's reporting and recordkeeping regulations (31 CFR part 1000). NCUA examiners review the programs to determine whether the credit union's procedures comply with the Bank Secrecy Act requirements. The requirement that credit unions establish written BSA compliance procedures is a one-time event, but revisions to those procedures must occur as deemed necessary.

NCUA examiners review the written procedures during examinations in order to ensure the implementation of adequate systems for complying with the BSA and its implementing regulations.

The NCUA requests that you send your comments on this collection to the location listed in the **ADDRESSES** section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Proposal for the following collection of information:

OMB Number: 3133–0108.

Form Number: None.

Type of Review: Reinstatement of a previously approved collection.

Title: Monitoring Bank Secrecy Act Compliance.

Description: The collection is needed to allow NCUA to determine whether credit unions have established a program reasonably designed to assure and monitor their compliance with currency recordkeeping and reporting requirements established by Federal statute and Department of Treasury Regulations.

Respondents: Federally Insured Credit Unions.

Estimated No. of Respondents/ Recordkeepers: 6,753.

Estimated Burden Hours per Response: 16 hours.

Frequency of Response: Annually.

Estimated Total Annual Burden Hours: 108,048.

Estimated Total Annual Cost: 0.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board

[FR Doc. 2013–17338 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, With Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). This information collection is published to obtain comments from the public. NCUA has authorized federal credit unions to advance money to members to cover account deficits without having a credit application on file if the credit union has a written overdraft policy. 12 CFR 701.21(c)(3). NCUA has also authorized federally insured credit unions to offer lending-related incentive pay to employees, provided they establish written policies regarding such plans. 12 CFR 701.21(c)(8).

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov*.

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is reinstating the collection of information for 3133–0139. NCUA has authorized federal credit unions to advance money to members to cover account deficits without having a credit application on file if the credit union has a written overdraft policy. 12 CFR 701.21(c)(3). NCUA believes a written policy is necessary to ensure safety and soundness in the credit union industry and to protect the interests of credit union members where a federal credit union provides overdraft protection to a member without having his or her credit application on file. NCUA has also authorized federally insured credit unions to offer lending-related incentive pay to employees, provided they establish written policies regarding such plans. 12 CFR 701.21(c)(8). NCUA believes those written policies are necessary to ensure a plan is fully considered before being adopted and for the examination process. NCUA examiners use the information in these policies to review for safety and soundness. This submission represents an adjustment to the recordkeeping hour and cost burden since the last submission. Based on information in March 2013 call reports, we estimate approximately 1,725 federal credit unions are required to have written overdraft policies and approximately 575 federally insured credit unions are required to have written policies for lending-related employee incentive pay plans.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: Organization and Operations of Federal Credit Unions (12 CFR part 701), (*previously titled* Overdraft and Lending-Related Employee Incentive Pay Plan Policies).

OMB Number: 3133–0139.

Form Number: None.

Type of Review: Reinstatement, with change, of a previously approved collection.

Description: Federal credit unions wishing to advance money to members to cover account deficits without having a credit application on file must establish a written overdraft policy. Federally insured credit unions wishing to pay lending-related incentives to employees must establish written policies.

Respondents: Certain Federal and federally insured credit unions.

Estimated No. of Respondents/ Recordkeepers: 2,300.

Estimated Burden Hours per Response: 3 hours for overdraft policy and 2 hours for lending-related employee incentive pay plan policies.

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 6,325 hours.

Estimated Total Annual Cost: $158,125.

By the National Credit Union Administration Board, on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17350 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities; Submission to OMB for Reinstatement, With Change, of a Previously Approved Collection

ACTION: Notice and request for comments.

SUMMARY: The NCUA, as part of their continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). NCUA is soliciting comments concerning the Suspicious Activity Report (SAR). As Bank Secrecy Act (BSA) administrator, the Financial Crimes Enforcement Network (FinCEN) transitioned from a system originally designed for collecting industry specific paper forms to a modernized information technology environment centered on electronic reporting. Based on financial institution type, depository institutions, broker-dealers in securities, futures commission merchants and introducing brokers in commodities, insurance companies, mutual funds, money services businesses, and casinos currently filed reports on four separate forms. FinCEN's objective is to have one electronically-filed dynamic and interactive BSA–SAR that will be used by all filing institutions to report suspicious activity as of April 1, 2013.

There are no proposed changes to the regulatory reporting criteria for information collection. Federally

insured credit unions will continue to follow the regulation, interagency guidance, and filing instructions to determine when a report should be filed and what information should be included on the report.

The interactive BSA–SAR includes several new data fields and introduces data fields from the SARs of other industries. On March 29, 2012, FinCEN released guidance [1] titled, ''Filing FinCEN's new Currency Transaction Report and Suspicious Activity Report''. This guidance clarified expectations and notes that FinCEN is making available additional and more specific data elements (i.e., characterizations of suspicious activity and types of financial services) as a more efficient way to bring information about suspicious activity to the attention of FinCEN and law enforcement. The guidance clarified the addition of new and expanded data elements; however, the guidance does not create an expectation that financial institutions will revise internal programs, or develop new programs, to capture information that reflects the expanded lists.

Additional information about the paperwork burden associated with these requirements, including statutory and regulatory history, a description of the reporting requirements, and how the estimated total annual burden was calculated, is discussed below.

Background and Justification

Since 1996, the federal banking agencies [2] and FinCEN have required certain types of financial institutions to report known or suspected violations of law and suspicious transactions. To fulfill these requirements, supervised banking organizations file Suspicious Activity Reports.[3] Law enforcement agencies use the information submitted on the reporting form to initiate investigations and Federal Reserve staff use the information in the examination and oversight of supervised institutions.

The NCUA's suspicious activity reporting rules apply to all federally insured credit unions. The NCUA is only responsible for the paperwork burden imposed on these institutions. Other federal banking agencies account for the paperwork burden for the institutions they supervise. The annual burden per respondent varies depending on the nature of the activity being reported.

The suspicious activity report filing requirement became effective on April 1, 1996. Prior to the effective date, the NCUA, the other federal banking agencies, and FinCEN each issued new and nearly identical rules mandating the use of the interagency SAR–DI for the reporting of suspicious activities. In separate actions, FinCEN also enacted regulations requiring other types of financial institutions, such as brokers or dealers in securities and futures; money services businesses (money transmitters; issuers and sellers of money orders and travelers' checks; check cashers, and dealers in foreign exchange); casinos and card clubs; and insurance companies to file reports on suspicious activities.

In January 2003, check boxes were added to Part III of the SAR–DI to note terrorist financing and identity theft as suspicious activities and the safe harbor language in the instructions was updated to reflect changes made by the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001. In 2006, the SAR–DI form was revised to support a new joint filing initiative aimed at reducing the total number of duplicate reports filed for a single suspicious transaction. On May 1, 2007, FinCEN published a **Federal Register** notice (72 FR 23891) [4] announcing the delayed implementation of these revisions, which ultimately were never implemented.

On July 15, 2011, FinCEN received final approval of the BSA–SAR [5] from the Office of Management and Budget which concluded FinCEN's October 15, 2010, request for comment.

Description of Information Collection

Federally insured credit unions follow the SAR instructions to determine when a SAR should be filed and what information should be included on the SAR.

Proposed Revisions

The BSA–SAR would integrate four institution specific SARs into one universal data collection. The previous five parts of the SAR–DI remain with changes to their titles and placement in order of completion.

The proposed BSA–SAR is described below by form Part. Fields from other industry SARs that may be new to depository institutions as well as specific data fields that are new to all types of industry filers have been identified. In the description provided below, questions for which an answer must be provided (referred to as ''critical fields'') are identified with the * symbol in front of the data element number.

Type of Filing

Field 1 is the Type of Filing and it would require the filer to designate the category that best describes the filing from the choices of:

* 1. Check all that apply—a. Initial report; b. Correct/amend prior report; c. Continuing activity report; d. Joint report; e. Prior report document control/file number if 1b or 1c are checked

On the current SAR–DI there is only one choice in data field 1 for those reports that corrected a prior report.

Part I: Subject Information

Part I is titled Subject Information and would require the filer to provide information for *each* subject involved in the suspicious activity. Subject Information is titled *Suspect* Information on the current SAR–DI. As with the existing SAR–DI, multiple subjects may be included in Part I.

Each of the critical fields (*) in this Part have a new check box that may be used if the information is unknown. If that box is checked, the filer would not need to enter any information in that field.

In Part I, with the exception of the unknown check box, these data fields would remain the same with no additions or changes from the SAR–DI:

* 3. Individual's last name or entity's legal name—a. (check if) unknown
* 4. First name—a. (check if) unknown
5. Middle initial (middle name for electronic filers)
7. Occupation or type of business
* 8. Address—a. (check if) unknown
* 9. City—a. (check if) unknown
* 10. State—a. (check if) unknown
* 11. ZIP/Postal Code—a. (check if)
* 12. Country Code—a. (check if) unknown
* 13. TIN—a. (check if) unknown
* 16. Date of birth mm/dd/yyyy—a. (check if) unknown

Listed below are the remaining data fields in Part I that would be considered new data fields or data fields that would be modified.

2. Check—a. If entity; b. If all critical (*) subject information is unavailable (If 2b is checked this Part may be left blank)
5a. Gender—b. (Check if) Male; c. (Check if) Female; d. (Check if) Unknown

[1] *http://www.fincen.gov/statutes_regs/guidance/pdf/FIN-2012-G002.pdf.*

[2] The Board of Governors of the Federal Reserve System, the Office of the Comptroller of the Currency, the Federal Deposit Insurance Corporation, and the National Credit Union Administration.

[3] In 1996, the NCUA, together with the other federal banking agencies issued nearly identical regulations to implement the SAR process for banking organizations.

[4] *http://www.fincen.gov/statutes_regs/frn/pdf/sar_fr_notice.pdf.*

[5] *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201104-1506-002.*

6. Alternate name, e.g. AKA for an Individual or DBA for an Entity
7a. NAICS Code (North American Industry Classification system code that corresponds to 7)
14. TIN type (* if 13 is completed)—a. EIN; b. SSN–ITIN; c. Foreign
* 15. Form of identification for subject—a. (check if) unknown (or not obtained); b. (check if) Driver's license/state ID; c. (check if) Passport; d. (check if) Alien registration; e. Number; f. Issuing state; g. Issuing country; z. (check if) Other
17. Phone number type—a. (check if) Home; b. (check if) Work; c. (check if) Mobile; d. (check if) Fax
18. Phone number—a. Extension (if any)
19. Email address (if available)
19a. Web site (URL) address (if available)
20. Corroborative statement to filer?—a. (check if) Yes; b. (check if) No (This was Admission/Confession on the SAR–DI)
21. Relationship of the subject to the filing institution (check all that apply)—a. Institution TIN; b. Accountant; c. Agent; d. Appraiser; e. Attorney; f. Borrower; g. Customer; h. Director; i. Employee; j. No relationship to institution; k. Officer; l. Owner or Controlling Shareholder; z. Other
22. If item 21h, 21i, 21j, or 21k is checked, indicate status of relationship—a. (check if) Relationship continues; b. (check if) Terminated; c. (check if) Suspended/barred; d. (check if) Resigned
23. Action date if 22 b, c, or d is checked
* 24. Financial Institution EIN and account number(s) affected that are related to subject, if any—a. (check if) No known account involved; b. (check if) Non-US Financial Institution; c. TIN; d. account number; e. (check if) closed;
25. Subject's role in suspicious activity (if applicable); a. (check if) Purchaser/Sender; b. (check if) Payee/Receiver; c. (check if) Both a & b

Part II—Suspicious Activity Information

Part II, Suspicious Activity Information, would require the filer to describe the suspicious activity that occurred.

Part II items would cover all filer institution types so all filers would see field options that may not pertain to their report (such as casino activities). Filers would only be required to complete those items that apply to their institution and pertain to the report being filed.

In Part II, with the exception of the unknown check box, these data fields would remain the same as the current SAR–DI:

* 27. Date or date range of suspicious activity for this report—a. From: mm/dd/yyyy; b. To: mm/dd/yyyy

The remaining data fields in this Part, specifically the characterizations of suspicious activity, would be modified and expanded when compared to the current SAR–DI. There are now ten general categories and each category would be further broken down to specific types of suspicious activity.

* 26. Amount involved in this report—a. (check if) Amount unknown; b. (check if) No amount involved.
28. Cumulative amount only if box 1c (continuing activity report) is checked
29. Structuring—a. Alters transaction to avoid BSA recordkeeping requirement; b. Alters transactions to avoid CTR requirement; c. Customer cancels transaction to avoid BSA reporting and recordkeeping requirements; d. Multiple transactions below BSA recordkeeping threshold; e. Multiple transactions below CTR threshold; f. Suspicious inquiry by customer regarding BSA reporting or recordkeeping requirements; z. Other (specify type of suspicious activity in space provided)
30. Terrorist Financing—a. Known or suspected terrorist/terrorist organization; z. Other (specify type of suspicious activity in space provided)
31. Fraud (Type)—a. ACH; b. Business loan; c. Check; d. Consumer loan; e. Credit/Debit card; f. Healthcare; g. Mail; h. Mass-marketing; i. Pyramid scheme; j. Wire; z. Other (specify type of suspicious activity in space provided)
32. Casinos—a. Inquiry about end of business day; b. Minimal gaming with large transactions; c. Suspicious intra-casino funds transfers; d. Suspicious use of counter checks or markers; z. Other (specify type of suspicious activity in space provided)
33. Money laundering—a. Exchanges small bills for large bills or vice versa; b. Suspicion concerning the physical condition of funds; c. Suspicion concerning the source of funds; d. Suspicious designation of beneficiaries, assignees or joint owners; e. Suspicious EFT/wire transfers; f. Suspicious exchange of currencies; g. Suspicious receipt of government payments/benefits; h. Suspicious use of multiple accounts; i. Suspicious use of noncash monetary instruments; j. Suspicious use of third-party transactors (straw-man); k. Trade Based Money Laundering/Black Market Peso Exchange; l. Transaction out of pattern for customer(s); z. Other (specify type of suspicious activity in space provided)
34. Identification/Documentation—a. Changes spelling or arrangement of name; b. Multiple individuals with same or similar identities; c. Provided questionable or false documentation; d. Refused or avoided request for documentation; e. Single individual with multiple identities; z. Other
35. Other suspicious activities—a. Account takeover; b. Bribery or gratuity; c. Counterfeit instruments; d. Elder financial exploitation; e. Embezzlement/theft/disappearance of funds; f. Forgeries; g. Identity theft; h. Little or no concern for product performance penalties, fees, or tax consequences; i. Misuse of ''free look''/cooling off/right of rescission; j. Misuse of position or self-dealing; k. Suspected public/private corruption (domestic); l. Suspected public/private corruption (foreign); m. suspicious use of informal value transfer system; n. Suspicious use of multiple transaction locations; o. Transaction with no apparent economic, business, or lawful purpose; p. Two or more individuals working together; q. Unauthorized electronic intrusion; r. Unlicensed or unregistered MSB; z. Other (specify type of suspicious activity in space provided)
36. Insurance—a. Excessive insurance; b. Excessive or unusual cash borrowing against policy/annuity; c. Proceeds sent to or received unrelated third party; d. Suspicious life settlement sales insurance (e.g. STOLI's, Viaticals); e. Suspicious termination of policy or contract; f. Unclear or no insurable interest; z. Other (specify type of suspicious activity in space provided)
37. Securities/Futures/Options—a. Insider trading; b. Market manipulation/wash trading; c. Misappropriation; d. Unauthorized pooling; z. Other (specify type of suspicious activity in space provided)
38. Mortgage fraud—a. Appraisal fraud; b. Foreclosure fraud; c. Loan modification fraud; d. Reverse mortgage fraud; z. Other
39. Were any of the following instrument/product type(s)

involved in the suspicious activity? Check all that apply: a. Bonds/Notes; b. Commercial mortgage; c. Commercial paper; d. Credit card; e. Debit card; f. Forex transactions; g. Futures/Options on futures; h. Hedge fund; i. Home equity loan; j. Home equity line of credit; k. Insurance/Annuity products; l. Mutual fund; m. Options on securities; n. Penny stocks/Microcap securities; o. Prepaid access; p. Residential mortgage; q. Security futures products; r. Stocks; s. Swap, hybrid or other derivative; z. Other (specify type in space provided)

40. Were any of the following instrument type(s)/payment mechanism(s) involved in the suspicious activity? Check all that apply—a. Bank/Cashier's check; b. Foreign currency; c. Funds transfer; d. Gaming instruments; e. Government payment; f. Money orders; g. Personal/Business check; h. Travelers check; i. U.S. Currency; z. Other (specify type in space provided)
41. Commodity type (if applicable)
42. Product/Instrument description (if needed)
43. Market where traded (list of codes will be provided—dropdown menu for electronic filers)
44. IP Address (if available) (multiple entries allowed for electronic filers)
45. CUSIP number (multiple entries allowed for electronic filers)
46. CUSIP number (multiple entries allowed for electronic filers)

Part III—Information About Financial Institution Where Activity Occurred

Part III information would be about the financial institution(s) where the suspicious activity occurred. A separate Part III record would be completed on each financial institution involved in the suspicious activity. The data fields in Part III would be modified and expanded when compared to the current SAR–DI.

* 47. Type of financial institution (check only one)—a. Casino/Card club; b. Depository institution; c. Insurance company; d. MSB; e. Securities/Futures; z. Other (specify type of institution in space provided)
* 48. Primary Federal Regulator—A = Commodities Futures Trading Commission (CFTC); B = Federal Reserve Board (FRB); C = Federal Deposit Insurance Corporation (FDIC); D = Internal Revenue Service (IRS); E = National Credit Union Administration (NCUA); F = Office of the Comptroller of the Currency (OCC); G = Securities and Exchange Commission (SEC); Z = Not Applicable
49. If item 47a is check indicate type (Check only one)—a. State licensed casino; b. Tribal authorized casino; c. Card club; d. Other (specify)
50. If item 47e is checked, indicate type of Securities and Futures institution or individual where activity occurred—check box(es) for functions that apply to this report—a. Clearing broker-securities; b. Futures Commission Merchant; c. Holding company; d. Introducing broker-commodities; e. Introducing broker-securities; f. Investment Advisor; g. Investment company; h. Retail foreign exchange dealer; i. Subsidiary of financial/bank holding company; z. Other *(specify type of institution or individual in space provided)*
51. Financial institution identification number (Check one box to indicate type)—a. (check if) CRD number; b. (check if) IARD number; c. (check if) NFA number; d. (check if) RSSD number; e. (check if) SEC number; f. Identification number
52. Financial institution's role in transaction (if applicable)—a. (check if) Selling location; b. (check if) Paying location; (check if) Both a & b
* 53. Legal name of financial institution—a. (check if) unknown
54. Alternate name, e.g., AKA—individual or trade name, DBA—entity
* 55. TIN—a. (check if) unknown
56. TIN type (* if 55 is completed)—a. EIN; b. SSN–ITIN; c. Foreign
* 57. Address—a. (check if) unknown
* 58. City—a. (check if) unknown
59. State
* 60 ZIP/Postal Code—a. (check if) unknown
* 61. Country
62. Internal control/file number
63. Loss to financial institution (if applicable)
64. Branch's role in transaction (if applicable)—a. (check if) Selling location; b. (check if) Paying location; c. (check if) Both a & b
* 65. Address of branch or office where activity occurred—a. (if no branch activity involved, check box a)
66. RSSD number (of the branch)
67. City
68. State
69. ZIP/Postal Code
70. Country (2 letter code—list provided)

Part IV—Filing Institution Contact Information

Part IV information would be about the lead financial institution or holding company that is filing the BSA–SAR. There would be only one Part IV record for each filing. Part IV would take fields previously contained in Part I, Part III, and Part IV on the SAR–DI as well as added new fields.

* 78. Primary Federal Regulator—A = Commodities Futures Trading Commission (CFTC); B = Federal Reserve Board (FRB); C = Federal Deposit Insurance Corporation (FDIC); D = Internal Revenue Service (IRS); E = National Credit Union Administration (NCUA); F = Office of the Comptroller of the Currency (OCC); G = Securities and Exchange Commission (SEC); Z = Not Applicable
* 79. Filer name (Holding company, lead financial institution)
* 80. TIN
* 81. TIN type—a. EIN; b. SSN/ITIN; c. Foreign
* 82. Type of financial institution (check only one)—a. Casino/Card club; b. Depository institution; c. Insurance company; d. MSB; e. Securities/Futures; z. Other (specify type of institution in space provided)
83. Type of Securities and Futures institution or individual filing this report-check box(es) for function that apply to this report—a. Clearing broker—securities; b. CPO/CTA; c. Futures Commission Merchant; d. Holding company; e. Introducing broker—commodities; f. Introducing broker—securities; g. Investment Adviser; h. Investment company; i. Retail foreign exchange dealer; j. SRO Futures; k. SRO Securities; l. Subsidiary of financial/bank holding company; z. Other (specify type of institution or individual in space provided)
84. Filing institution identification number (Check one box to indicate type)—a. (check if) CRD number; b. (check if) IARD number; c. (check if) NFA number; d. (check if) RSSD number; e. (check if) SEC number; f. Identification number
* 85. Address
* 86. City
87. State
* 88. ZIP/Postal Code
* 89. Country
90. Alternate name, e.g., AKA—individual or trade name, DBA—entity
91. Internal control/file number
92. LE contact agency
93. LE contact name
94. LE contact phone number—a. Extension (if any)
95. LE contact date
* 96. Designated contact office
* 97. Designated contact office phone number including area code—a. Extension (if any)

* 98. Date filed

Part V—Suspicious Activity Information Explanation/Description

Part V would require the filer to provide a chronological and complete narrative account of the activity, including what is unusual, irregular, or suspicious about the activity. In the BSA–SAR this part would be a text file that is limited to 17,000 characters (approximately six pages). Institutions may, but are not required to, attach a MS Excel-compatible file (no larger than 1 MB) providing details in tabular form of transactions subject to the suspicious activity discussed in the text file.

Consultation Outside the Agency

As set forth above, the SAR was originally developed in 1996 by an interagency group that consisted of the federal banking agencies, the U.S. Departments of Justice and Treasury, and several law enforcement agencies. The general framework of the BSA–SAR report and revisions to the BSA–SAR data elements have been discussed on an interagency basis.

Estimate of Respondent Burden

The burden per institution varies depending on the nature of the activity being reported. Because of these changes to the BSA–SAR, the estimated average burden would increase to 2 hours per response. Between January 1, 2012, and December 31, 2012, federally insured credit unions filed 67,537 [6] SARs. Based on this data the annual reporting burden for the federally insured credit unions is estimated to be 135,074 hours with the proposed revisions.

DATES: Written comments should be received on or before September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov*.

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the collection, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

Title: Suspicious Activity Report by Depository Institutions (SAR).

OMB Control Numbers: 3133–0094.

Form Numbers: 2362.

Abstract: In 1985, the Banking Supervisory Agencies issued procedures to be used by banks and certain other financial institutions operating in the United States to report known or suspected criminal activities to the appropriate law enforcement and Banking Supervisory Agencies. Beginning in 1994, the Banking Supervisory Agencies and FinCEN redesigned the reporting process resulting in the Suspicious Activity Report, which became effective in April 1996. The report is authorized by 12 CFR 748.1 (NCUA). The regulation was issued under the authority contained in 1789(a) (NCUA).

Current Action: NCUA proposes to renew, with revision, the previously approved form.

Type of Review: Reinstatement of a previously approved collection.

Affected Public: Business, for-profit institutions, and non-profit institutions.

Estimated Number of Respondents: 6,753.

Estimated Total Annual Responses: 67,537.

Estimated Total Annual Burden: at an estimated 2 hours per form, Total Annual Burden is 135,074 hours.

Records required to be retained under the Bank Secrecy Act and these regulations issued by the Banking Supervisory Agencies must be retained for five years. Generally, information collected pursuant to the Bank Secrecy Act is confidential, but may be shared as provided by law with regulatory and law enforcement authorities.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology, and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17352 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

[6] *The SAR Activity Review—By the Numbers; Issue 18*

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, Without Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). This information collection is published to obtain comments from the public. The information collection applies to credit unions that engage in member business lending and requires written loan policies that address the various aspects of the member business loan program. Credit unions desiring a waiver from appraisal requirements, aggregate construction and development loan, loan-to-value ratios, personal liability and guarantee requirements, unsecured lending limits to one borrower, aggregate unsecured lending limits, or outstanding loans to one borrower limits of Part 723 must submit certain information to NCUA for consideration. Finally, a credit union seeking regulatory approval to purchase certain business loans in addition to those, which are statutorily limited, must submit certain information to NCUA for consideration.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov*.

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the

National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Request for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is amending/reinstating the collection for 3133–0101. Part 723 of NCUA's regulations implements provisions in the Federal Credit Union Act (Act) for business loans and addresses NCUA's safety and soundness concerns regarding this activity. Part 723 requires that credit unions that engage in business lending maintain written loan policies that address various aspects of the activity, including identification of the types of business loans the credit union will make, qualifications of loan officers, documentation requirements for creditworthiness of borrowers, collateral requirements, loan procedures, interest rates and maturities, and so forth. 12 CFR 723.6. Business lending is recognized as inherently riskier than consumer lending and requires particular expertise. Before promulgation of the member business loan regulation in the 1980s, business loans caused significant losses to the credit unions and the National Credit Union Share Insurance Fund (NCUSIF). Requiring federally-insured credit unions to develop specific business loan policies and procedures protects the safety and soundness of credit unions and the NCUSIF.

Part 723 also permits credit unions to apply for a waiver from certain regulatory requirements. 12 CFR 723.10-.11. Specifically, the rule permits waivers from the following requirements or limitations: appraisal requirements, aggregate construction and development loan limits, minimum borrower equity requirements for construction and development loans, loan-to-value ratios, personal liability and guarantee requirements, unsecured lending limits to one borrower, aggregate unsecured lending limits, and outstanding loans to one borrower limits. NCUA needs certain information from a credit union to consider the waiver request and evaluate the risks and impact of the waiver on the credit union and potential effect on the NCUSIF.

Finally, Part 723 permits a credit union to obtain regulatory approval so that it may purchase certain business purpose loans in addition to those which are statutorily limited. 12 CFR 723.16(b)(2). NCUA needs certain information from a credit union to evaluate its request so that NCUA may assess safety and soundness considerations and potential effect on the NCUSIF.

NCUA examiners review the credit union policies during regulatory examinations. These reviews allow examiners to determine the appropriateness and risks of the programs they address for both the credit union and the NCUSIF. Written policies enable examiners to determine that the credit union is, in fact, following its own business planning in engaging member business lending. As part of the examination process, this review helps prevent losses to credit unions and the NCUSIF.

For waiver requests, the information in the requests permits NCUA staff to make a reasonable determination of the appropriateness of the requests. For loan approval requests, the information in the requests permits NCUA staff to determine the appropriateness and risks of the loan purchases the credit union proposes for both the credit union and the NCUSIF.

An increase in the reporting burden from the prior submission occurred due to an adjustment to the estimated responses based upon current credit union activity. While the number of respondents decreased, the estimated waiver activity increased resulting in an overall increase in annual response hours.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

OMB Number: 3133–0101.

Form Number: N/A.

Type of Review: Reinstatement, without change.

Title: 12 CFR Parts 723.5—Develop written loan policies—and 723.11—Provide waiver requests.

Description: The general purpose of the requirements imposed by the rule is to ensure that loans are made, documented, and accounted for properly and for the ultimate protection of the National Credit Union Share Insurance Fund. Respondents are federally insured credit unions who make business loans as defined in the regulation.

Respondents: Federally Insured Credit Unions.

Estimated No. of Respondents/Recordkeepers: 1,116.

Estimated Burden Hours per Response: 4–17 hours.

Frequency of Response: Recordkeeping, reporting and on occasion.

Estimated Total Annual Burden Hours: 9,492 hours.

Estimated Total Annual Cost: $0.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17342 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, With Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). This information collection is published to obtain comments from the public. The collection requires each Federal Credit Union (FCU) to establish reasonable policies and procedures for implementing the guidelines to identify possible risks to account holders or customers or to the safety and soundness of the institution or creditor (Red Flag Regulations). Each FCU is also required to develop an Identity Theft Prevention Program, provide staff training, and report to the board of directors, a committee thereof, or senior

management at least annually. In addition, credit and debit card issuers are generally required to assess the validity of change of address requests.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444. E&I Contact: Program Officer Judy Graham *eimail@ncua.gov,* 703–518–6360.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is reinstating and amending/the collection for 3133–0175. This collection of information is required by sections 114 and 315 of the FACT Act. The NCUA is renewing its collection and removing the burden attributable to the portion of the regulations transferred to the Bureau of Consumer Financial Protection (CFPB) pursuant to title X of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1955, July 21, 2010 (Dodd-Frank Act), and republished as CFPB regulations (76 FR 79308 (December 21, 2011)). The transferred regulations, which relate to address discrepancies, were found at 12 CFR part 717, and are now contained in 12 CFR 1022.82. The burden estimates for this portion of the collection have been revised to remove the burden attributable to NCUA-regulated credit unions with over $10 billion in total assets, now carried by CFPB pursuant to section 1025 of the Dodd-Frank Act. The NCUA retains enforcement authority under 12 CFR 1022.82 for its institutions with total assets of $10 billion or less.

As required by section 114 of the FACT Act, appendix J to 12 CFR part 717 contains guidelines for financial institutions and creditors to use in identifying patterns, practices, and specific forms of activity that indicate the possible existence of identity theft. In addition, 12 CFR 717.90 requires each financial institution or creditor to establish reasonable policies and procedures to address the risk of identity theft that incorporate the guidelines. Pursuant to section 717.91, credit card and debit card issuers must implement reasonable policies and procedures to assess the validity of a request for a change of address under certain circumstances.

Section 717.90 requires each NCUA regulated FCUs that offers or maintains one or more covered accounts to develop and implement a written Identity Theft Prevention Program (Program). In developing the Program, financial institutions and creditors are required to consider the guidelines in appendix J and include those that are appropriate. The initial Program must be approved by the board of directors or an appropriate committee thereof. The board, an appropriate committee thereof, or a designated employee at the level of senior management must be involved in the oversight of the Program. In addition, staff members must be trained to carry out the Program. Pursuant to section 717.91, each credit and debit card issuer is required to establish and implement policies and procedures to assess the validity of a change of address request under certain circumstances. Before issuing an additional or replacement card, the card issuer must notify the cardholder or use another means to assess the validity of the change of address.

As required by section 315 of the FACT Act, section 1022.82 requires users of consumer reports to have reasonable policies and procedures that must be followed when a user receives a notice of address discrepancy from a credit reporting agency (CRA).

Section 1022.82 requires each user of consumer reports to develop and implement reasonable policies and procedures designed to enable the user to form a reasonable belief that a consumer report relates to the consumer about whom it requested the report when it receives a notice of address discrepancy from a CRA. A user of consumer reports also must develop and implement reasonable policies and procedures for furnishing an address for the consumer that the user has reasonably confirmed to be accurate to the CRA from which it receives a notice of address discrepancy when the user can: (1) Form a reasonable belief that the consumer report relates to the consumer about whom the user has requested the report; (2) establish a continuing relationship with the consumer and; (3) establish that it regularly and in the ordinary course of business furnishes information to the CRA from which it received the notice of address discrepancy.

Burden estimate: The hourly burden increased despite a decline in respondents due to an increase in the estimated processing times. NCUA estimates 4,206 respondents with assets of $10 million or less. Each FCU requires 111 hours annually for a total of 466,866 hours annually.

NCUA estimates of the 4,206 annual respondents annually, 2 are new FCUs requiring a one-time additional 250 hours for program development. New FCUs incur an additional 500 hours annually.

NCUA's estimated total annual burden is 467,366 hours. Based upon the 111 hours for the annual program and additional 250 hours for new FCU program development.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden hours of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: Identity Theft Red Flags and Address Discrepancies under the FACT Act of 2003 (FACTA), 12 CFR Part 717.

OMB Number: 3133–0175.

Form Number: None.

Type of Review: Reinstatement, with change, of a previously approved collection.

Description: The NCUA and other agencies published a rule to implement sections 114 and 315 of the FACTA by proposing guidelines for identifying patterns, practices and specific forms of activity indicative of possible identity theft. 71 FR 63718 (Nov. 9, 2007). The Agencies also issued regulations that would require financial institutions and creditors to establish policies and procedures to implement the guidelines, including assessing the validity of

address change requests. Pursuant to title X of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1955, July 21, 2010 (Dodd-Frank Act), the Bureau of Consumer Financial Protection (CFPB) reissued its portion of the regulation as CFPB regulations (76 FR 79308 (December 21, 2011)).

Respondents: Federal Credit Unions.

Estimated No. of Respondents/Record keepers: 4,206.

Estimated Burden Hours per Response: 111 hours.

Frequency of Response: Initial and Annual.

Estimated Total Annual Burden Hours: 467,366

Estimated Total Annual Cost: N/A.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17345 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, Without Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). This information collection is published to obtain comments from the public. Part 741, Section 741.11 of the NCUA Rules and Regulations contains a provision that any insured credit union must apply for and receive approval from the regional director before establishing a credit union branch outside the United States unless the foreign branch is located on a United States military institution or embassy outside the United States.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is amending/reinstating the collection for 3133–0167. The collection of information requirement is that any insured credit union must apply for and receive approval from the NCUA Regional Director before establishing a credit union branch outside the United States unless the foreign branch is located on a United States military institution or embassy outside the United States. The application must include (1) a business plan, (2) written approval by the state supervisory agency if the applicant is a state-chartered credit union, and (3) documentation evidencing written permission from the host country to establish the branch that explicitly recognizes NCUA's authority to examine and take any enforcement actions, including conservatorship and liquidation actions. There is no change to the burden hours from previous submissions.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: 12 CFR part 741.11 of NCUA's Rules and Regulations, Foreign Branching.

OMB Number: 3133–0167.

Form Number: None.

Type of Review: Reinstatement, without change, of a previously approved collection.

Description: Part 741.11 contains a provision that any insured credit union must apply for and receive approval from the NCUA Regional Director before establishing a credit union branch outside the United States unless the foreign branch is located on a United States military institution or embassy outside the United States. The application must include (1) a business plan, (2) written approval by the state supervisory agency if the applicant is a state-chartered credit union, and (3) documentation evidencing written permission from the host country to establish the branch that explicitly recognizes NCUA's authority to examine and take any enforcement actions, to include conservatorship and liquidation actions.

Estimated No. of Respondents/ Recordkeepers: 3.

Estimated Burden Hours per Response: 16 hours.

Frequency of Response: Reporting and other (one time only).

Estimated Total Annual Burden Hours: 48.

Estimated Total Annual Cost: $ 1,488.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17339 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, Without Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). This information collection is published to obtain comments from the public and is required under Section 205 of the Federal Credit Union Act (FCU Act) to allow federally-insured credit unions (FICUs) to purchase assets or assume liabilities of privately-insured credit unions, other financial institutions, or their successor in interest.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is reinstating the collection for 3133–0169. FICUs will apply to the NCUA for approval to purchase assets or assume liabilities of privately-insured credit unions or other financial institutions. NCUA will use the information in the application to determine the safety and soundness of the transaction and risk to the National Credit Union Share Insurance Fund (NCUSIF).

NCUA anticipates a FICU's application for approval to purchase assets or assume liabilities of a privately-insured credit union or other financial institution would consist of a cover letter and any transaction documents already prepared by the FICU in conjunction with the anticipated purchase or assumption. NCUA believes this would take one hour or less to prepare and transmit the cover letter and attach any additional documents; therefore, there is no increase or decrease in the burden for this data collection. The term ''transaction documents'' include contracts, agreements, letters, offers, or similar documents already created between two parties as evidence of a transaction or negotiation. NCUA does not require FICUs to prepare these documents and believes they are created in the regular course of business. Therefore, NCUA has used one burden hour per credit union per filing required from an FICU to prepare a letter requesting NCUA's approval of the transaction and describing the transaction.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: Purchase of Assets and Assumptions of Liabilities.

OMB Number: 3133–0169.

Form Number: None.

Type of Review: Reinstatement without change.

Description: This information collection is required under Section 205 of the Federal Credit Union Act (FCU Act) to allow federally-insured credit unions (FICUs) to purchase assets or assume liabilities of privately-insured credit unions, other financial institutions, or their successor in interest.

Respondents: FICUs will apply to the NCUA for approval to purchase assets or assume liabilities of privately-insured credit unions or other financial institutions.

Estimated No. of Respondents/Recordkeepers: 5.

Estimated Burden Hours per Response: 1 hour.

Frequency of Response: Reporting and on occasion.

Estimated Total Annual Burden Hours: 5 hours.

Estimated Total Annual Cost: None.

By the National Credit Union Administration Board, on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17354 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, With Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). This information collection notice is published to obtain comments from the public. This is related to NCUA's regulation on mergers of federally-insured credit unions and voluntary termination or conversion of insured status.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOMail@ncua.gov.*

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is reinstating a previously approved collection of information for 12 CFR part 708b, Mergers of Federally-Insured Credit Unions; Voluntary Termination or Conversion of Insured Status. The Federal Credit Union Act (Act) authorizes the NCUA Board to prescribe rules regarding mergers of federally-insured credit unions and changes in insured status and requires written approval of the Board before one or more federally-insured credit union(s) merge or before a federally-insured credit union terminates federal

share insurance or converts to nonfederal share insurance. 12 U.S.C. 1752(7), 1766(a), 1785(b), 1785(c), and 1789(a). Part 708b of NCUA's rules sets forth the procedural and disclosure requirements for mergers of federally-insured credit unions, federal share insurance terminations, and conversions from federal share insurance to nonfederal (private) insurance. The rule is designed to ensure NCUA has sufficient information to determine whether to approve a proposed merger, share insurance termination, or share insurance conversion. It further ensures that members of credit unions have sufficient and accurate information to exercise their vote properly concerning a proposed merger, insurance termination, or insurance conversion. The rule also protects the property interests of members who may lose their federal share insurance due to a merger, share insurance termination, or share insurance conversion. 12 CFR part 708b.

The categories of burden for credit unions complying with part 708b may include the following:

Mergers

Each year, there are approximately 240 mergers involving federally-insured credit unions (both natural person and corporate credit unions). NCUA estimates it will take two merging credit unions approximately 35 hours between them to:

a. Prepare the required merger documents (§ 708b.103);

b. Collect and submit the required information to NCUA (§ 708b.104);

c. Provide the required insurance disclosures in other communications that the credit union plans to send to its members if the merger involves a share insurance conversion (§ 708b.206);

d. Notify members of the merger and send them the ballot (§§ 708b.106, 708b.303(a), 708b.303(b));

e. Notify NCUA of the results of the merger vote (§§ 708b.107, 708b.303(c));

f. Notify NCUA of the merger's completion (§ 708b.108); and

g. Notify members of the results of the merger and the possible effect on their insurance coverage (§ 708b.101(e)).

The 240 respondents (the two merging credit unions together treated as one respondent) times 35 hours per respondent equals 8,400 total annual burden hours associated with this collection of information.

Share Insurance Termination

Typically, no credit unions each year engage in share insurance terminations. If one or more credit unions were to engage in a voluntary termination of insurance in the future, NCUA estimates there will be minimal burden in the form of collections of information on those credit unions. NCUA estimates it will take each credit union approximately 12 hours to:

a. Prepare the required termination documents and submit the required information to NCUA (§ 708b.201);

b. Notify the members and send them the ballot (§ 708b.202);

c. Provide the required insurance disclosures in other communications that the credit union plans to send to its members (§ 708b.206);

d. Notify NCUA of the results of the termination vote (§ 708b.201(d)(2)); and

e. Provide members notice of termination of insurance (§ 708b.202(c)).

Zero respondents times 12 hours per respondent equals zero total annual burden hours associated with this collection of information.

Share Insurance Conversions

Approximately two credit unions each year engage in private share insurance conversions outside of the merger context. NCUA estimates there will be minimal burden in the form of collections of information, since NCUA provides forms and form language in the regulation. NCUA estimates that it will take each credit union approximately 12 hours to:

a. Prepare the required conversion documents and submit the required information to NCUA (§§ 708b.203, 708b.301(a));

b. Notify members of the conversion and send them the ballot (§§ 708b.204, 708b.301(b) and (c));

c. Provide the required insurance disclosures in other communications that the credit union plans to send to its members (§ 708b.206);

d. Notify NCUA of the results of the conversion vote (§ 708b.301(d)); and

e. Provide members notice of conversion of insurance (§ 708b.204(c)).

Two respondents times 12 hours per respondent equals 24 total annual burden hours associated with this collection of information.

The NCUA requests that you send your comments on this collection for part 708b to the locations listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

OMB Number: 3133—0024.

Form Number: None.

Title: Mergers of Federally-Insured Credit Unions; Voluntary Termination or Conversion of Insured Status, 12 CFR part 708b.

Type of Review: Reinstatement, with change, of a previously approved collection.

Description: Part 708b of NCUA's rules sets forth the procedural and disclosure requirements for mergers of federally-insured credit unions, federal share insurance terminations, and conversions from federal share insurance to nonfederal (private) insurance. Submission of this information is designed to ensure NCUA has sufficient information whether to approve a proposed merger, share insurance termination, or share insurance conversion. It further ensures that members of credit unions have sufficient and accurate information to exercise their vote properly concerning a proposed merger, insurance termination, or insurance conversion. The rule also protects the property interests of members who may lose their federal share insurance due to a merger, share insurance termination, or share insurance conversion.

Respondents: Federally-insured credit unions.

Estimated No. of Respondents: 242.

Frequency of Response: Once; On occasion.

Estimated Time per Response: Ranges from 12 to 35 hours.

Estimated Total Annual Burden Hours: 8,424 hours.

Estimated Total Annual Cost: $336,960.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17343 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, Without Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). This information collection is published to obtain comments from the public. Section 741.2 of the NCUA Rules and Regulations (12 CFR part 741) places a maximum borrowing limit on federally insured credit unions. State chartered federally insured credit unions must seek a waiver of the borrowing limit from the NCUA Regional Director prior to exceeding this limitation.

DATES: Comments will be accepted until September 17, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: OCIOPRA@ncua.gov.

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is reinstating the collection for 3133–0168. The collection of information requirement is for those state chartered federal insured credit unions seeking a waiver from the borrowing limit. These credit unions must submit a detailed safety and soundness analysis, a proposed aggregate amount, a letter from the state regulator approving the request and an explanation of the need for the waiver to the NCUA Regional Director. This collection of information is necessary to protect the National Credit Union Share Insurance Fund (''Fund''). The NCUA Board has determined that borrowing in excess of 50 percent of paid-in and unimpaired capital and surplus may cause an undue risk to the Fund and a loss of confidence in the credit union system. The NCUA must be made aware of and be able to monitor those credit unions seeking a waiver from the requirement. There is no change in burden hours from previous submission.

The NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: Maximum Borrowing Authority, 12 CFR 741.2.

OMB Number: 3133–0168.

Form Number: None.

Type of Review: Reinstatement, without change, of a previously approved collection.

Description: 5 CFR 741.2 places a maximum borrowing limitation on federally insured credit unions of 50 percent of paid-in and unimpaired capital and surplus. The collection of information requirement is for those federally insured state-chartered credit unions seeking a waiver from the maximum borrowing limitation of 50 percent of paid-in and unimpaired capital and surplus. These credit unions must submit a detailed safety and soundness analysis, a proposed aggregate amount, a letter from the state regulator approving the request and an explanation of the need for the waiver to the NCUA Regional Director.

Respondents: Credit unions.

Estimated No. of Respondents/Record keepers: 2.

Estimated Burden Hours per Response: 8 hours.

Frequency of Response: Reporting, and on occasion.

Estimated Total Annual Burden Hours: 16 hours.

Estimated Total Annual Cost: $496.

By the National Credit Union Administration Board on July 15, 2013.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17349 Filed 7–18–13; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meeting

TIME AND DATE: 10:00 a.m., Wednesday, July 24, 2013.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Consideration of Supervisory Activities. Closed pursuant to the following Exemptions: (8), (9)(i)(B) and (9)(ii).

2. Personnel. Closed pursuant to Exemption (2).

FOR FURTHER INFORMATION CONTACT: Mary Rupp, Secretary of the Board, Telephone: 703–518–6304.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2013–17536 Filed 7–17–13; 4:15 pm]

BILLING CODE 7535–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act Meeting

TIME AND DATE: 2:00 p.m., Wednesday, September 11, 2013.

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue NW., Washington, DC.

STATUS: Hearing open to the public at 2:00 p.m.

PURPOSE: Public Hearing in conjunction with each meeting of OPIC's Board of Directors, to afford an opportunity for any person to present views regarding the activities of the Corporation.

PROCEDURES: Individuals wishing to address the hearing orally must provide advance notice to OPIC's Corporate Secretary no later than 5 p.m. Friday, September 6, 2013. The notice must include the individual's name, title, organization, address, and telephone number, and a concise summary of the subject matter to be presented.

Oral presentations may not exceed ten (10) minutes. The time for individual

presentations may be reduced proportionately, if necessary, to afford all participants who have submitted a timely request an opportunity to be heard.

Participants wishing to submit a written statement for the record must submit a copy of such statement to OPIC's Corporate Secretary no later than 5 p.m. Friday, September 6, 2013. Such statement must be typewritten, double-spaced, and may not exceed twenty-five (25) pages.

Upon receipt of the required notice, OPIC will prepare an agenda, which will be available at the hearing, that identifies speakers, the subject on which each participant will speak, and the time allotted for each presentation.

A written summary of the hearing will be compiled, and such summary will be made available, upon written request to OPIC's Corporate Secretary, at the cost of reproduction.

Written summaries of the projects to be presented at the September 19, 2013 Board meeting will be posted on OPIC's Web site on or about Thursday, August 29, 2013.

CONTACT PERSON FOR INFORMATION: Information on the hearing may be obtained from Connie M. Downs at (202) 336–8438, via facsimile at (202) 408–0297, or via email at *Connie.Downs@opic.gov*.

Dated: July 17, 2013.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 2013–17537 Filed 7–17–13; 4:15 pm]

BILLING CODE 3210–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2013–55 and CP2013–73; Order No. 1777]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 61 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 22, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a request and associated supporting information to add Priority Mail Contract 61 to the competitive product list.[1] It asserts that Priority Mail Contract 61 is a competitive product ''not of general applicability'' within the meaning of 39 U.S.C. 3632(b)(3). Request at 1. The Request has been assigned Docket No. MC2013–55.

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B. The instant contract has been assigned Docket No. CP2013–73.

Request. To support its Request, the Postal Service filed six attachments as follows:

- Attachment A—a redacted copy of Governors' Decision No. 11–6, authorizing the new product;
- Attachment B—a redacted copy of the contract;
- Attachment C—proposed changes to the Mail Classification Schedule competitive product list with the addition underlined;
- Attachment D—a Statement of Supporting Justification as required by 39 CFR 3020.32;
- Attachment E—a certification of compliance with 39 U.S.C. 3633(a); and
- Attachment F—an application for non-public treatment of materials to maintain redacted portions of the contract and related financial information under seal.

In the Statement of Supporting Justification, Dennis R. Nicoski, Manager, Field Sales Strategy and Contracts, asserts that the contract will cover its attributable costs and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.* Attachment D at 1. Mr. Nicoski contends that there will be no issue of market dominant products subsidizing competitive products as a result of this contract. *Id.*

Related contract. The Postal Service included a redacted version of the related contract with the Request. *Id.* Attachment B. The contract is scheduled to become effective one business day after the Commission issues all necessary regulatory approval. *Id.* at 2. The contract will expire three years from the effective date unless, among other things, either party terminates the agreement upon 90 days' written notice to the other party. *Id.* at 3. The contract also allows two 90-day extensions of the agreement if the preparation of a successor agreement is active and the Commission is notified.[2] The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a).[3]

The Postal Service filed much of the supporting materials, including the related contract, under seal. *Id.* Attachment F. It maintains that the redacted portions of the Governors' Decision, contract, customer-identifying information, and related financial information should remain confidential. *Id.* at 3. This information includes the price structure, underlying costs and assumptions, pricing formulas, information relevant to the customer's mailing profile, and cost coverage projections. *Id.* The Postal Service asks the Commission to protect customer-identifying information from public disclosure indefinitely. *Id.* at 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2013–55 and CP2013–73 to consider the Request pertaining to the proposed Priority Mail Contract 61 product and the related contract, respectively.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart

[1] Request of the United States Postal Service to Add Priority Mail Contract 61 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, July 12, 2013 (Request).

[2] *Id.* In Docket Nos. MC2013–54 and CP2013–70, the Postal Service clarified that identical language in Priority Mail Contract 60 ''contemplates the Postal Service filing any notices of extension with the Commission at least one week prior to the 3-year expiration date or the extended expiration date.'' *See* Docket Nos. MC2013–54 and CP2013–70, Order No. 1773, Order Adding Priority Mail Contract 60 to the Competitive Product List, July 8, 2013; *see also* Docket Nos. MC2013–54 and CP2013–70, Response of the United States Postal Service to Chairman's Information Request No. 1, July 1, 2013, at question 2.

[3] Although the Notice appears to state that the certification only pertains to paragraphs (1) and (3) of 39 U.S.C. 3633(a), the certification itself contains an assertion that the ''prices are in compliance with 39 U.S.C. 3633 (a)(1), (2), and (3).'' Request at 2 and Attachment E.

B. Comments are due no later than July 22, 2013. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2013–55 and CP2013–73 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than July 22, 2013.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2013–17300 Filed 7–18–13; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2013–15; Order No. 1779]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the amendment to Priority Mail Contract 48 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 23, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On July 12, 2013, the Postal Service filed notice that it has agreed to an amendment to Priority Mail Contract 48.[1] The Notice includes a redacted version of the amendment to Priority Mail Contract 48 (Amendment) and the certified statement and supporting financial information required by 39 CFR 3015.5(c) relating to the change in prices.

The Amendment changes the prices that apply to packages sent under Priority Mail Contract 48 as well as the parameters for packages considered ''Contract Packages'' under the contract. Notice, Attachment A at 1. It is scheduled to take effect one business day after the Commission completes its review of the Amendment. *Id.*

The Postal Service's Notice contained the Amendment as Attachment A, the certified statement as Attachment B, and sought to incorporate by reference the original application for non-public treatment in this docket. Notice at 1.

In the certified statement required by 39 CFR 3015.5, Steven R. Phelps, Manager, Regulatory Reporting and Cost Analysis, Finance Department, states that the amended prices and terms are consistent with Governors Decision No. 11–6 and 39 U.S.C. 3633(a) *Id.,* Attachment B. He concludes that the contract is expected to cover its attributable costs and will not result in the subsidization of competitive products by market dominant products. *Id.*

II. Notice of Filing

Interested persons may submit comments on whether the changes presented in the Postal Service's Notice and Supplement are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020 subpart B. Comments are due no later than July 23, 2013. The public portions of these filings can be accessed via the Commission's Web site (*www.prc.gov*). Information on how to obtain access to non-public material appears at 39 CFR 3007.40.

James F. Callow will continue to serve as the Public Representative in this proceeding.

III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. CP2013–15 for consideration of matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, James F. Callow will continue to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments are due no later than July 23, 2013.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2013–17371 Filed 7–18–13; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Change in Prices Pursuant to Amendment to Priority Mail Contract 48, July 12, 2013 (Notice).

POSTAL REGULATORY COMMISSION

[Docket No. MC2013–56 and CP2013–74; Order No. 1778]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 62 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 22, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a request and associated supporting information to add Priority Mail Contract 62 to the competitive product list.[1] It asserts that Priority Mail

[1] Request of the United States Postal Service to Add Priority Mail Contract 62 to Competitive

Contract 62 is a competitive product ''not of general applicability'' within the meaning of 39 U.S.C. 3632(b)(3). Request at 1. The Request has been assigned Docket No. MC2013–56.

The Postal Service contemporaneously filed a redacted contract related to the proposed new product. *Id.* Attachment B. The instant contract has been assigned Docket No. CP2013–74.

Request. To support its Request, the Postal Service filed six attachments as follows:

- Attachment A—a redacted copy of Governors' Decision No. 11–6, authorizing the new product;
- Attachment B—a redacted copy of the contract;
- Attachment C—proposed changes to the Mail Classification Schedule competitive product list with the addition underlined;
- Attachment D—a Statement of Supporting Justification as required by 39 CFR 3020.32;
- Attachment E—a certification of compliance with 39 U.S.C. 3633(a); and
- Attachment F—an application for non-public treatment of materials to maintain redacted portions of the contract and related financial information under seal.

In the Statement of Supporting Justification, Dennis R. Nicoski, Manager, Field Sales Strategy and Contracts, asserts that the contract will cover its attributable costs and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.* Attachment D at 1. Mr. Nicoski contends that there will be no issue of market dominant products subsidizing competitive products as a result of this contract. *Id.*

Related contract. The Postal Service included a redacted version of the related contract with the Request. *Id.* Attachment B. The contract is scheduled to become effective one business day after the Commission issues all necessary regulatory approval. *Id.* at 2. The contract will expire three years from the effective date unless, among other things, either party terminates the agreement upon 30 days' written notice to the other party. *Id.* at 3. The contract also allows two 90-day extensions of the agreement if the preparation of a successor agreement is active and the Commission is notified.[2] The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a).[3]

The Postal Service filed much of the supporting materials, including the related contract, under seal. *Id.* Attachment F. It maintains that the redacted portions of the Governors' Decision, contract, customer-identifying information, and related financial information should remain confidential. *Id.* at 3. This information includes the price structure, underlying costs and assumptions, pricing formulas, information relevant to the customer's mailing profile, and cost coverage projections. *Id.* The Postal Service asks the Commission to protect customer-identifying information from public disclosure indefinitely. *Id.* at 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2013–56 and CP2013–74 to consider the Request pertaining to the proposed Priority Mail Contract 62 product and the related contract, respectively.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than July 22, 2013. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Lyudmila Y. Bzhilyanskaya to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2013–56 and CP2013–74 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than July 22, 2013.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2013–17305 Filed 7–18–13; 8:45 am]

BILLING CODE 7710–FW–P

Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, July 12, 2013 (Request).

[2] *Id.* In Docket Nos. MC2013–54 and CP2013–70, the Postal Service clarified that identical language in Priority Mail Contract 60 ''contemplates the Postal Service filing any notices of extension with the Commission at least one week prior to the 3-year expiration date or the extended expiration date.'' *See* Docket Nos. MC2013–54 and CP2013–70, Order No. 1773, Order Adding Priority Mail Contract 60 to the Competitive Product List, July 8, 2013; *see also* Docket Nos. MC2013–54 and CP2013–70, Response of the United States Postal Service to Chairman's Information Request No. 1, July 1, 2013, at question 2.

[3] Although the Notice appears to state that the certification only pertains to paragraphs (1) and (3) of 39 U.S.C. 3633(a), the certification itself contains an assertion that the ''prices are in compliance with 39 U.S.C. 3633 (a)(1), (2), and (3).'' *Id.* at 2 and Attachment E.

POSTAL SERVICE

Privacy Act of 1974; System of Records

AGENCY: Postal Service™.

ACTION: Notice of modification to existing systems of records.

SUMMARY: The United States Postal Service® is proposing to modify four General Privacy Act Systems of Records. These updates are being made to account for additional methods that the Postal Service uses to contact applicants, employees, and former employees. Additionally, changes are being made to one record system to include assessments of postal employees and to expand the locations where information from such assessments may be stored. Lastly, changes are being made to another record system pertaining to personnel research to include former Postal Service employees as a category of individuals covered by that system and to modify one of the purposes of the system.

DATES: These revisions will become effective without further notice on August 19, 2013 unless comments received on or before that date result in a contrary determination.

ADDRESSES: Comments may be mailed or delivered to the Records Office, United States Postal Service, 475 L'Enfant Plaza SW., Room 9431, Washington, DC 20260–1101. Copies of all written comments will be available at this address for public inspection and photocopying between 8 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Matthew J. Connolly, Chief Privacy Officer (A), Privacy and Records Office, 202–268–8582.

SUPPLEMENTARY INFORMATION: This notice is in accordance with the Privacy Act requirement that agencies publish their amended systems of records in the **Federal Register** when there is a revision, change, or addition. The Postal Service™ has reviewed these systems of

records and has determined that these four General Privacy Act Systems of Records should be revised to modify system location, categories of individuals covered by the system, categories of records in the system, purpose(s), retreivability, notification procedure, and record source categories.

I. Background

The U.S. Postal Service has, as a necessary practice since the inception of its online application process, collected the personal email addresses of applicants and potential applicants as a means of communication. The proposed changes are intended to account for such collection.

Additionally, over the next few years, a substantial portion of the current Postal Service leadership will be eligible to retire. Moreover, a significant organizational transition is changing the competencies and skills that are needed by up-and-coming leadership. Therefore, it is critically important that the Postal Service be ready to assess the capabilities of existing and potential leaders by providing tailored assessments that adequately measure characteristics that are linked directly to the leadership competency models, thereby allowing the Postal Service to identify, develop, and hire top talent into leadership positions. The proposed changes are intended to facilitate such assessments and the storage of information generated from such assessments.

Lastly, the proposed changes are intended to provide Human Resources with the option of contacting former employees, via their personal email addresses, for the purpose of obtaining feedback that will enable the Postal Service to continuously improve its processes.

II. Rationale for Changes to USPS Privacy Act Systems of Records

The systems of records 100.000 General Personal Records and 100.100 Recruiting, Examining, and Placement Records are being modified to account for the collection of personal email addresses from applicants and potential applicants who then become employees.

Additionally, the system of records 100.300 Employee Development and Training Records is being updated to facilitate the assessment services of contractors as part of its continued effort to develop and hire talent into leadership positions.

Lastly, the Postal Service is also proposing additional changes to system of records 100.600 Personnel Research to facilitate assessments by Human Resources of the impact of selection decisions on applicants within specific demographic categories, including, among other categories, veteran status. Among other things, these changes will enable the Postal Service to obtain feedback from applicants, potential applicants, employees, and former employees via their personal email addresses so that the Postal Service may continuously improve its processes. A minor change is also being made to clarify that Employee Identification Numbers, which are used to identify postal employees in other records systems, will be a category of records in this system.

III. Description of Changes to Systems of Records

The Postal Service is modifying four systems of records listed below. Pursuant to 5 U.S.C. 552a (e)(11), interested persons are invited to submit written data, views, or arguments on this proposal. A report of the proposed modifications has been sent to Congress and to the Office of Management and Budget for their evaluation. The Postal Service does not expect this amended notice to have any adverse effect on individual privacy rights. The affected systems are as follows:

USPS 100.000

System Name: General Personnel Records

USPS 100.100

System Name: Recruiting, Examining, and Placement Records

USPS 100.300

System Name: Employee Development and Training Records

USPS 100.600

System Name: Personnel Research Records

Accordingly, for the reasons stated, the Postal Service proposes changes in the existing system of records as follows:

USPS 100.000

SYSTEM NAME:

General Personnel Records.

CATEGORIES OF RECORDS IN THE SYSTEM:

* * * * *

[CHANGE TO READ]

1. *Employee, former employee, and family member information:* Name(s), Social Security Number(s), Employee Identification Number, date(s) of birth, place(s) of birth, marital status, postal assignment information, work contact information, home address(es) and phone number(s), personal email address, finance number(s), duty location, and pay location.

* * * * *

USPS 100.100

SYSTEM NAME:

Recruiting, Examining, and Placement Records.

CATEGORIES OF RECORDS IN THE SYSTEM:

* * * * *

[CHANGE TO READ]

1. Applicant, potential applicants with candidate profiles, and employee information: Name(s), Social Security Number(s), Candidate Identification Number, Employee Identification Number, date(s) of birth, postal assignment or vacancy/job posting history information, work contact information, home address(es) and phone number(s), personal email address, finance number(s), duty location, and pay location.

* * * * *

USPS 100.300

SYSTEM NAME:

Employee Development and Training Records.

SYSTEM LOCATION:

[CHANGE TO READ]

Management training centers, Integrated Business Solutions Services Centers, other USPS facilities where career development and training records are stored, and contractor sites.

CATEGORIES OF RECORDS IN THE SYSTEM:

* * * * *

[CHANGE TO READ]

2. Employee development and training information: Records related to career development, work history, assessments, skills bank participation, USPS- and non-USPS-sponsored training, examinations, evaluations of training, and USPS lodging when a discrepancy report is filed against the student about unauthorized activities while occupying the room.

* * * * *

USPS 100.600

SYSTEM NAME:

Personnel Research Records.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

[CHANGE TO READ]

Potential applicants for USPS employment, applicants for USPS employment, USPS employee applicants for reassignment and/or promotion, employees whose work records or solicited responses are used in research projects, and former USPS employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

[CHANGE TO READ]

1. Applicant, potential applicant with candidate profile, and employee information: Name, Social Security Number, Candidate Identification Number, Employee Identification Number (EIN), or respondent identification code, place of birth, postal assignment or vacancy/posting information, work contact information, home address and phone number(s), personal email address, finance number(s), duty location, and pay location.

2. Personnel research information: Records related to race, ethnicity, sex, tenure, age, veteran status, and disability status (only if volunteered by the individual); research project identifiers; and other information pertinent to personnel research.

* * * * *

PURPOSE(S):

* * * * *

[CHANGE TO READ]

2. To assess the impact of selection decisions on applicants in race, ethnicity, sex, tenure, age, veteran status, and disability categories.

* * * * *

RETRIEVABILITY:

By individual name, Social Security Number, Candidate Identification Number, Employee Identification Number, personal email address, respondent identification code, research project identifiers, postal assignment or vacancy/posting information, duty or pay location, or location where data were collected.

* * * * *

NOTIFICATION PROCEDURE:

Individuals wanting to know if information about them is maintained in this system of records must address inquiries to the Vice President, Employee Resource Management, 475 L'Enfant Plaza SW., Washington, DC 20260. In cases of studies involving information not collected through an examination, individuals must address inquiries to the system manager. Inquiries must contain full name; Candidate Identification Number, Employee Identification Number, or respondent identification code, and subject or purpose of research/survey; and date and location of their participation.

* * * * *

RECORD SOURCE CATEGORIES:

USPS employees, former employees, applicants, and potential applicants with candidate profiles who provide information to personnel research programs and other systems of records.

* * * * *

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–17325 Filed 7–18–13; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 19, 2013.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 12, 2013, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 62 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2013–56, CP2013–74.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–17323 Filed 7–18–13; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 19, 2013.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 12, 2013, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 61 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2013–55, CP2013–73.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–17322 Filed 7–18–13; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–2013.

Extension:

Rule 602. SEC File No. 270–404, OMB Control No. 3235–0461.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 602 of Regulation NMS (17 CFR 240.602), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 602 of Regulation NMS, Dissemination of Quotations in NMS securities, contains two related collections. The first collection of information is found in Rule 602(a).[1] This third-party disclosure requirement obligates each national securities exchange and national securities association to make available to quotation vendors for dissemination to the public the best bid, best offer, and aggregate quotation size for each ''subject security,'' as defined under the Rule. The second collection of information is found in Rule 602(b).[2] This disclosure requirement obligates any exchange member and over-the-counter (''OTC'') market maker that is a ''responsible broker or dealer,'' as defined under the Rule, to communicate to an exchange or association its best bids, best offers, and quotation sizes for subject securities.[3]

[1] 17 CFR 242.602(a).

[2] 17 CFR 242.602(b).

[3] Under Rule 602(b)(5), electronic communications networks (''ECNs'') have the

Continued

It is anticipated that 17 respondents, consisting of 16 national securities exchanges and one national securities association, will collectively respond approximately 839,944,682,631 times per year pursuant to Rule 602(a) at 18.22 microseconds per response, resulting in a total annual burden of approximately 4,250 hours.

It is anticipated that approximately 150 respondents, consisting of OTC market makers, will collectively respond approximately 28,200,000 times per year pursuant to Rule 602(b) at 3 seconds per response, resulting in a total annual burden of approximately 23,500 hours.

Thus, the aggregate third-party disclosure burden under Rule 602 is 27,750 hours annually which is comprised of 4,250 hours relating to Rule 602(a) and 23,500 hours relating to Rule 602(b).

Written comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (b) the accuracy of the Commission's estimate of the burden of the proposed collections of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of collections of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number. Please direct your written comments to: Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*.

option of reporting to an exchange or association for public dissemination, on behalf of customers that are OTC market makers or exchange market makers, the best-priced orders and the full size for such orders entered by market makers on the ECN, to satisfy such market makers' reporting obligation under Rule 602(b). Since this reporting requirement is an alternative method of meeting the market makers' reporting obligation, and because it is directed to nine or fewer persons (ECNs), this collection of information is not subject to OMB review under the Paperwork Reduction Act (''PRA'').

Dated: July 15, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–17315 Filed 7–18–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Form N–CSR. SEC File No. 270–512, OMB Control No. 3235–0570

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form N–CSR (17 CFR 249.331 and 274.128) is a combined reporting form used by registered management investment companies (''funds'') to file certified shareholder reports under the Investment Company Act of 1940 (15 U.S.C. 80a–1 et seq.) (''Investment Company Act'') and the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.) (''Exchange Act''). Specifically, Form N–CSR is to be used for reports under section 30(b)(2) of the Investment Company Act (15 U.S.C. 80a–29(b)(2)) and section 13(a) or 15(d) of the Exchange Act (15 U.S.C. 78m(a) and 78o(d)), filed pursuant to rule 30b2–1(a) under the Investment Company Act (17 CFR 270.30b2–1(a)). Reports on Form N CSR are to be filed with the Securities and Exchange Commission (''Commission'') no later than 10 days after the transmission to stockholders of any report that is required to be transmitted to stockholders under rule 30e–1 under the Investment Company Act (17 CFR 270.30e–1).

Form N–CSR is filed semi-annually, and the Commission estimates that there are 3,288 respondents. The Commission also estimates that the average number of portfolios referenced in each filing is 3.75. The Commission further estimates that the hour burden for preparing and filing a report on Form N–CSR is 7.21 hours per portfolio. Given that filings on Form N–CSR are filed semi-annually, filings on Form N–CSR require 14.42 hours per portfolio each year. The total annual hour burden for Form N–CSR, therefore, is estimated to be 177,799 hours. The estimated total annual cost burden to respondents for outside professionals associated with the collection of data relating to Form N–CSR is $3,189,771.

The collection of information under Form N–CSR is mandatory. Responses to the collection of information will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, C/O Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 15, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–17313 Filed 7–18–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 17a–3(a)(16). SEC File No. 270–452, OMB Control No. 3235–0508.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. Sec. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') is

soliciting comments on the collection of information provided for in Rule 17a–3(a)(16) (17 CFR 240.17a–3(a)(16)) under the Securities Exchange Act of 1934 (15 U.S.C. 78q *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17a–3(a)(16) identifies the records required to be made by broker-dealers that operate internal broker-dealer systems. Those records are to be used in monitoring compliance with the Commission's financial responsibility program and antifraud and antimanipulative rules, as well as other rules and regulations of the Commission and the self-regulatory organizations. It is estimated that approximately 105 active broker-dealer respondents registered with the Commission incur an average aggregate burden of 2,835 hours per year (105 respondents multiplied by 27 burden hours per respondent equals 2,835 total burden hours) to comply with this rule.[1]

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 15, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–17314 Filed 7–18–13; 8:45 am]

BILLING CODE 8011–01–P

[1] The average cost per hour is $269. Therefore the total internal cost of compliance for the respondents is $762,615.

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 30599; 812–14110]

Grosvenor Alternative Funds Master Trust, et al.; Notice of Application

July 15, 2013.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act and rule 18f–2 under the Act, as well as from certain disclosure requirements.

SUMMARY: *Summary of Application:* Applicants request an order that would permit them to enter into and materially amend subadvisory agreements without shareholder approval and would grant relief from certain disclosure requirements.

Applicants: Grosvenor Alternative Funds Master Trust (''Master Trust''), Grosvenor Alternative Funds (''GAF Trust''), and Grosvenor Capital Management, L.P. (the ''Initial Adviser'') (collectively, ''Applicants'').

DATES:

Filing Dates: The application was filed on January 8, 2013, and amended on May 10, 2013.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 9, 2013 and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: Girish Kashyap, Grosvenor Capital Management, L.P., 900 North Michigan Avenue, Suite 1100, Chicago, IL 60611.

FOR FURTHER INFORMATION CONTACT: Courtney S. Thornton, Senior Counsel, at (202) 551–6812, or David P. Bartels, Branch Chief, at (202) 551–6821 (Division of Investment Management, Exemptive Applications Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Master Trust [1] and the GAF Trust (collectively with the Master Trust, ''Trusts'') will be registered under the Act as open-end management investment companies organized as Delaware statutory trusts.[2] Each Trust will offer one or more series (each a ''Fund'' and collectively the ''Funds''), each of which has or will have its own distinct investment objectives, policies and restrictions.[3] The Initial Adviser, an Illinois limited partnership, is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). The Initial Adviser will serve as investment adviser to each Fund pursuant to an investment advisory agreement (''Advisory Agreement'') with the respective Fund.[4]

[1] Applicants state that each series of the Master Trust is a master fund (''Master Fund'') in a master-feed structure pursuant to section 12(d)(1)(E) of the Act. Certain Funds (as defined below), as well as any future Fund and any other investment company or series thereof that is advised by the Initial Adviser (as defined below), may invest substantially all their assets in the Master Fund (each a ''Feeder Fund''). No Feeder Fund will engage any subadviser other than through approving the applicable Master Fund's subadviser, if any.

[2] Applicants also request relief with respect to any future Fund as well as any other existing or future registered open-end management investment company or series thereof that: (a) is advised by the Initial Adviser or any entity controlling, controlled by, or under common control with the Initial Adviser or its successors (collectively, the ''Adviser''); (b) uses the manager of managers structure (''Manager of Managers Structure'') described in the application; and (c) complies with the terms and conditions of the application (together with any Funds that currently use the Manager of Mangers Structure, each a ''Subadvised Fund'' and collectively, the ''Subadvised Funds''). The only existing registered open-end management investment companies that currently intend to rely on the requested order are named as applicants. For purposes of the requested order, ''successor'' is limited to an entity or entities that result from a reorganization into another jurisdiction or a change in the type of business organization. If the name of any Subadvised Fund contains the name of a Subadviser (as defined below), the name of the Adviser will precede the name of the Subadviser.

[3] The initial and current Fund of the Master Trust is Grosvenor Alternative Strategies Master Fund. The initial and current Fund of the GAF Trust is Grosvenor Alternative Strategies Fund.

[4] Applicants state that, under a master-feeder operating structure, the initial Fund in the GAF Trust is a Feeder Fund that pursues its investment objective by investing all of its investable assets in a corresponding series of the Master Trust having identical investment objectives to those of the

Continued

Each Advisory Agreement will be approved by the relevant Trust's board of trustees (the ''Board''), including a majority of the trustees who are not ''interested persons,'' as defined in section 2(a)(19) of the Act, of the Trust or the Adviser (''Independent Trustees'') and by the shareholders of the relevant Fund in the manner required by sections 15(a) and 15(c) of the Act and rule 18f–2 under the Act.

2. Under the terms of the Advisory Agreements, the Adviser, subject to the oversight of the Board, will furnish a continuous investment program for each Fund. The Adviser periodically reviews investment policies and strategies of each Fund and, based on the need of a particular Fund, may recommend changes to the investment policies and strategies of the Fund for consideration by its Board. For its services to each Fund, the Adviser will receive an investment advisory fee from that Fund as specified in the applicable Advisory Agreement based on the average daily net asset value of that Fund. The terms of the Advisory Agreements also permit the Adviser, subject to the approval of the relevant Board, including a majority of the Independent Trustees and the shareholders of the applicable Subadvised Funds (if required by applicable law), to delegate portfolio management responsibilities of all or a portion of the assets of the Subadvised Fund to one or more subadvisers (''Subadvisers''). The Adviser intends to enter into subadvisory agreements (''Subadvisory Agreements'') with various Subadvisers to provide investment advisory services to various Subadvised Funds. Each Subadviser will be an investment adviser as defined in section 2(a)(20) of the Act and registered with the Commission as an ''investment adviser'' under the Advisers Act. The Adviser will evaluate, allocate assets to and oversee the Subadvisers, and will make recommendations about their hiring, termination and replacement to the Board, at all times subject to the authority of the Board. The Adviser will compensate each Subadviser out of the fee paid to the Adviser under the relevant Advisory Agreement, or the Subadvised Fund will be responsible for paying subadvisory fees directly to the Subadviser.[5]

3. The Subadvised Funds will inform shareholders of the hiring of a new Subadviser pursuant to the following procedures (''Modified Notice and Access Procedures''): (a) within 90 days after a new Subadviser is hired for any Subadvised Fund, that Subadvised Fund will send its shareholders[6] either a Multi-Manager Notice or a Multi-Manager Notice and Multi-Manager Information Statement;[7] and (b) the Subadvised Fund will make the Multi-Manager Information Statement available on the Web site identified in the Multi-Manager Notice no later than when the Multi-Manager Notice (or Multi-Manager Notice and Multi-Manager Information Statement) is first sent to shareholders, and will maintain it on that Web site for at least 90 days.

4. Applicants request an order to permit the Adviser, subject to Board approval, to select Subadvisers to manage all or a portion of the assets of a Subadvised Fund pursuant to a Subadvisory Agreement and to materially amend Subadvisory Agreements without obtaining shareholder approval. The requested relief will not extend to any Subadviser that is an affiliated person, as defined in section 2(a)(3) of the Act, of a Feeder Fund or a Subadvised Fund or the Adviser, other than by reason of serving as a Subadviser to a Subadvised Funds (''Affiliated Subadviser'').

5. Applicants also request an order exempting the Subadvised Funds from certain disclosure provisions described below that may require the Applicants to disclose fees paid by the Adviser or a Subadvised Fund to each Subadviser. Applicants seek an order to permit each Subadvised Fund to disclose (as a dollar amount and a percentage of each Subadvised Fund's net assets) only: (a) the aggregate fees paid to the Adviser and any Affiliated Subadvisers; and (b) the aggregate fees paid to Subadvisers other than Affiliated Subadvisers (collectively, the ''Aggregate Fee Disclosure'').[8] A Subadvised Fund that employs an Affiliated Subadviser will provide separate disclosure of any fees paid to the Affiliated Subadviser.

Applicants' Legal Analysis

1. Section 15(a) of the Act provides, in relevant part, that it is unlawful for any person to act as an investment adviser to a registered investment company except pursuant to a written contract that has been approved by the vote of a majority of the company's outstanding voting securities. Rule 18f–2 under the Act provides that each series or class of stock in a series investment company affected by a matter must approve that matter if the Act requires shareholder approval.

2. Form N–1A is the registration statement used by open-end investment companies. Item 19(a)(3) of Form N–1A requires disclosure of the method and amount of the investment adviser's compensation.

3. Rule 20a–1 under the Act requires proxies solicited with respect to an investment company to comply with Schedule 14A under the Exchange Act. Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A, taken together, require a proxy statement for a shareholder meeting at which the advisory contract will be voted upon to include the ''rate of compensation of the investment adviser,'' the ''aggregate amount of the investment adviser's fees,'' a description of the ''terms of the contract to be acted upon,'' and, if a change in the advisory fee is proposed, the existing and proposed fees and the difference between the two fees.

4. Regulation S–X sets forth the requirements for financial statements required to be included as part of a registered investment company's registration statement and shareholder

Fund. All investment management for the Feeder Funds takes place at the Master Fund level and no investment management takes place at the Feeder Fund level. Investment management for any future Funds that do not operate under a master-feeder structure will occur at the Fund level.

[5] Under the requested order, for Subadvised Funds that pay fees to a Subadviser directly from Fund assets, any change to a Subadvisory Agreement or Investment Advisory Agreement that would not result in an increase in the total management and advisory fees payable by the Subadvised Fund would not need to be submitted to affected shareholders for approval. For instance, the management and advisory fees payable by a Subadvised Fund to a Subadviser could be increased without shareholder approval if there were a corresponding decrease in the management and advisory fees payable by the Subadvised Fund to the Adviser.

[6] If the Subadvised Fund is a Master Fund, for purposes of the Modified Notice and Access Procedures, ''shareholders'' include both the shareholders of the applicable Master Fund and the shareholders of its Feeder Funds.

[7] A ''Multi-Manager Notice'' will be modeled on a Notice of Internet Availability as defined in rule 14a-16 under the Securities Exchange Act of 1934 (''Exchange Act''), and specifically will, among other things: (a) Summarize the relevant information regarding the new Subadviser; (b) inform shareholders that the Multi-Manager Information Statement is available on a Web site; (c) provide the Web site address; (d) state the time period during which the Multi-Manager Information Statement will remain available on that Web site; (e) provide instructions for accessing and printing the Multi-Manager Information Statement; and (f) instruct the shareholder that a paper or email copy of the Multi-Manager Information Statement may be obtained, without charge, by contacting the Subadvised Fund. A ''Multi-Manager Information Statement'' will meet the requirements of Regulation 14C, Schedule 14C and Item 22 of Schedule 14A under the Exchange Act for an information statement, except as modified by the requested order to permit Aggregate Fee Disclosure (as defined below). Multi-Manager Information Statements will be filed electronically with the Commission via the EDGAR system.

[8] For any Subadvised Fund that is a Master Fund, applicants request that this relief also permit any Feeder Fund invested in that Master Fund to disclose Aggregate Fee Disclosure.

reports filed with the Commission. Sections 6–07(2)(a), (b) and (c) of Regulation S–X require a registered investment company to include in its financial statement information about the investment advisory fees.

5. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or from any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that the requested relief meets this standard for the reasons discussed below.

6. Applicants assert that the shareholders expect the Adviser, subject to the review and approval of the Board, to select the Subadvisers who are best suited to achieve the Subadvised Fund's investment objective. Applicants assert that, from the perspective of the shareholder, the role of the Subadviser is substantially equivalent to the role of the individual portfolio managers employed by an investment adviser to a traditional investment company. Applicants state that requiring shareholder approval of each Subadvisory Agreement would impose unnecessary delays and expenses on the Subadvised Funds, and enable the Subadvised Fund to act more quickly when the Board and the Adviser believe that a change would benefit a Subadvised Fund and its shareholders. Applicants note that the Investment Advisory Agreements and any Subadvisory Agreement with an Affiliated Subadviser (if any) will continue to be subject to the shareholder approval requirements of section 15(a) of the Act and rule 18f–2 under the Act.

7. Applicants assert that the requested disclosure relief would benefit shareholders of the Subadvised Funds because it would improve the Adviser's ability to negotiate the fees paid to Subadvisers. Applicants state that the Adviser may be able to negotiate rates that are below a Subadviser's ''posted'' amounts, if the Adviser is not required to disclose the Subadvisers' fees to the public. Applicants submit that the requested relief will encourage Subadvisers to negotiate lower subadvisory fees with the Adviser if the lower fees are not required to be made public.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Subadvised Fund may rely on the requested order, the operation of the Subadvised Fund in the manner described in the application will be approved by a majority of the Subadvised Fund's outstanding voting securities as defined in the Act, which in the case of a Master Fund will include voting instructions provided by shareholders of the Feeder Funds investing in such Master Fund or other voting arrangements that comply with section 12(d)(1)(E)(iii)(aa) of the Act, or, in the case of a Subadvised Fund whose public shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the initial shareholder before such Subadvised Fund's shares are offered to the public.

2. The prospectus for each Subadvised Fund, and in the case of a Master Fund relying on the requested relief, the prospectus for each Feeder Fund investing in such Master Fund, will disclose the existence, substance, and effect of any order granted pursuant to the application. In addition, each Subadvised Fund (and any such Feeder Fund) will hold itself out to the public as employing a Manager of Managers Structure. The prospectus will prominently disclose that the Adviser has the ultimate responsibility, subject to oversight by the Board, to oversee the Subadvisers and recommend their hiring, termination, and replacement.

3. Subadvised Funds will inform shareholders, and if the Subadvised Fund is a Master Fund, shareholders of any Feeder Funds, of the hiring of a new Subadviser within 90 days after the hiring of the new Subadviser pursuant to the Modified Notice and Access Procedures.

4. The Adviser will not enter into a Subadvisory Agreement with any Affiliated Subadviser without that agreement, including the compensation to be paid thereunder, being approved by the shareholders of the applicable Subadvised Fund, which in the case of a Master Fund will include voting instructions provided by shareholders of the Feeder Fund investing in such Master Fund or other voting arrangements that comply with Section 12(d)(1)(E)(iii)(aa) of the Act.

5. At all times, at least a majority of the Board will be Independent Trustees, and the nomination of new or additional Independent Trustees will be placed within the discretion of the then-existing Independent Trustees.

6. Independent legal counsel, as defined in rule 0–1(a)(6) under the Act, will be engaged to represent the Independent Trustees. The selection of such counsel will be within the discretion of the then-existing Independent Trustees.

7. Whenever a Subadviser change is proposed for a Subadvised Fund with an Affiliated Subadviser, the Board, including a majority of the Independent Trustees, will make a separate finding, reflected in the Board minutes, that the change is in the best interests of the Subadvised Fund and its shareholders, and if the Subadvised Series is a Master Fund, the best interests of any applicable Feeder Funds and their respective shareholders, and does not involve a conflict of interest from which the Adviser or the Affiliated Subadviser derives an inappropriate advantage.

8. Whenever a Subadviser is hired or terminated, the Adviser will provide the Board with information showing the expected impact on the profitability of the Adviser.

9. The Adviser will provide general management services to each Subadvised Fund, including overall supervisory responsibility for the general management and investment of the Subadvised Fund's assets and, subject to review and approval of the Board, will: (a) Set the Subadvised Fund's overall investment strategies; (b) evaluate, select and recommend Subadvisers to manage all or a portion of the Subadvised Fund's assets; (c) allocate and, when appropriate, reallocate the Subadvised Fund's assets among Subadvisers; (d) monitor and evaluate the Subadvisers' performance; and (e) implement procedures reasonably designed to ensure that Subadvisers comply with the Subadvised Fund's investment objective, policies and restrictions.

10. No Trustee or officer of a Subadvised Fund or of a Feeder Fund that invests in a Subadvised Fund that is a Master Fund, or director or officer of the Adviser, will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by such person) any interest in a Subadviser except for (a) ownership of interests in the Adviser or any entity that controls, is controlled by or is under common control with the Adviser; or (b) ownership of less than 1% of the outstanding securities of any class of equity or debt of any publicly traded company that is either a Subadviser or an entity that controls, is controlled by or is under common control with a Subadviser.

11. Each Subadvised Fund and any Feeder Fund that invests in a Subadvised Fund will disclose in its registration statement the Aggregate Fee Disclosure.

12. In the event the Commission adopts a rule under the Act providing

substantially similar relief to that in the order requested in the application, the requested order will expire on the effective date of that rule.

13. The Adviser will provide the Board, no less frequently than quarterly, with information about the profitability of the Adviser on a per Subadvised Fund basis. The information will reflect the impact on profitability of the hiring or termination of any Subadviser during the applicable quarter.

14. For Subadvised Funds that pay fees to a Subadviser directly from Fund assets, any changes to a Subadvisory Agreement that would result in an increase in the total management and advisory fees payable by a Subadvised Fund will be required to be approved by the shareholders of the Subadvised Fund.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–17316 Filed 7–18–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33–9418; 34–69988, File No. 265–28]

Dodd-Frank Investor Advisory Committee

AGENCY: Securities and Exchange Commission.

ACTION: Notice of Meeting of Securities and Exchange Commission Dodd-Frank Investor Advisory Committee.

SUMMARY: The Securities and Exchange Commission Investor Advisory Committee, established pursuant to Section 911 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, is providing notice that it will hold a public meeting on Thursday, July 25, 2013, in Multi-Purpose Room LL–006 at the Commission's headquarters, 100 F Street NE., Washington, DC 20549. The meeting will begin at 10:00 a.m. (EDT) and end at 4:00 p.m. and will be open to the public, except during portions of the meeting reserved for meetings of the Committee's subcommittees. The meeting will be webcast on the Commission's Web site at *www.sec.gov*. Persons needing special accommodations to take part because of a disability should notify the contact person listed below. The public is invited to submit written statements to the Committee. The agenda for the meeting includes approval of minutes, Investor as Owner Subcommittee recommendation regarding data tagging, Investor as Owner Subcommittee recommendation regarding the use of universal proxy ballots, and subcommittee reports.

DATES: Written statements should be received on or before July 25, 2013.

ADDRESSES: Written statements may be submitted by any of the following methods:

Electronic Statements

■ Use the Commission's Internet submission form (*http://www.sec.gov/rules/other.shtml*); or

■ Send an email message to *rules-comments@sec.gov.* Please include File No. 265–28 on the subject line; or

Paper Statements

■ Send paper statements in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. 265–28. This file number should be included on the subject line if email is used. To help us process and review your statement more efficiently, please use only one method.

Statements also will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Room 1580, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All statements received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: M. Owen Donley, Chief Counsel, at (202) 551–6322, Office of Investor Education and Advocacy, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

Dated: July 15, 2013.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2013–17303 Filed 7–18–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69987; File No. SR–CBOE–2013–026]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, Relating to Complex Orders

July 15, 2013.

I. Introduction

On March 28, 2013, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b-4 thereunder,[2] a proposed rule change to amend its rules governing the trading of complex orders on the Exchange to adopt a new order type called ''leg orders.'' On April 11, 2013, the Exchange filed Amendment No. 1 to the proposal. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on April 17, 2013.[3] The Commission received no comment letters regarding the proposed rule change, as modified by Amendment No. 1. On June 26, 2013, the Exchange filed Amendment No. 2 to the proposal.[4] The Commission is publishing this notice to solicit comments on Amendment No. 2 from interested persons and is approving the proposed rule change, as modified by Amendment Nos. 1 and 2, on an accelerated basis.

II. Description

A. Leg Orders

CBOE proposes to adopt CBOE Rule 6.53C(c)(iv) relating to the generation and execution of leg orders. A leg order would be a limit order on the CBOE electronic book (''EBook'') that represents one leg of a non-contingent complex order resting on the complex order book (''COB'') if the ratio of that leg to the other legs of the complex order is equal to or can be reduced to one (*e.g.,* 1:1, 1:2, or 1:3).[5] A leg order

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 69364 (April 11, 2013), 78 FR 22326.

[4] *See infra* Section II.B for a description of Amendment No. 2.

[5] *See* proposed CBOE Rule 6.53(x). *See also* Notice, 78 FR 22928, n. 4 for an explanation of conforming ratios as applied to the generation of leg orders.

would be a firm order that may be included in the Exchange's displayed best bid or offer (''Exchange BBO'') on the EBook.[6] According to CBOE, leg orders are designed to increase opportunities for complex orders resting on the COB to leg into the CBOE individual options market and execute.[7]

1. Generation of Leg Orders

CBOE proposes that leg orders may be automatically generated on behalf of complex orders so that they are represented in the individual leg markets.[8] CBOE proposes that a leg order would be automatically generated for a leg of a complex order resting on the top of the COB: (1) If the price of the complex order is inside the ''derived net market,'' which is based on the derived net price of the best-priced orders or quotes (other than leg orders) in the EBook; and (2) at a price at which the net price execution of the complex order can be achieved if the other leg(s) of the complex order executes against the best-priced orders or quotes (other than leg orders).[9] To determine whether leg orders may be generated or displayed in accordance with proposed CBOE Rule 6.53C(c)(iv)(1)(A)–(C), CBOE would evaluate the COB when a complex order enters the COB, when the Exchange BBO changes, and at a regular time interval to be determined by the Exchange (which would not exceed one second).[10]

CBOE states that the derived net market and the price of leg orders would be based on the best-priced non-leg orders in the other leg series, as those are the orders against which a complex order may execute.[11] CBOE proposes that the size of a leg order would be the lesser of (1) the size of the complex order, and (2) the maximum size available in the EBook for the other leg(s) of the complex order (divided by the leg ratio, if applicable).[12]

CBOE proposes that it may, on an objective basis, limit the number of leg orders generated.[13] According to CBOE, leg orders may be made available on a class-by-class basis and may not be available for all of its systems.[14] CBOE believes that this would help the Exchange manage the number of leg orders generated to ensure that leg orders do not negatively impact the Exchange's system capacity and performance.[15] CBOE represents that it would not limit the generation of leg orders on the basis of the entering participant or the participant category of the order (*i.e.,* professional, professional customer, or public customer).[16]

Finally, CBOE proposes not to generate a leg order if the price of the leg order would lock or cross the national best bid or offer (''NBBO'').[17] CBOE also proposes to not generate leg orders for stock-option orders.[18]

2. Display and Nondisplay of Leg Orders; Aggregation of Size

CBOE's proposed rule change specifies when a leg order would be displayed and when it would be nondisplayed. A leg order would only be displayed on the EBook if the price of the leg order matches or improves the Exchange BBO pursuant to proposed CBOE Rule 6.53C(c)(iv)(1)(B).[19] A leg order would not be displayed on the Ebook if the price of the leg order does not match or improve the Exchange BBO.[20] If multiple resting complex orders in *different* strategies generate leg orders for the same price on the same side of an options series and both leg orders are eligible for display (*i.e.,* both leg orders match or improve the Exchange BBO), then the leg order with the largest size would be displayed and the other leg orders would not be displayed.[21] If such leg orders are for the same size, then the first leg order generated would be displayed and the other leg order(s) would not be displayed.[22] If multiple resting complex orders in the *same* strategy generate leg orders for the same price on the same side of an options series, then the sizes of the leg orders would be aggregated and treated as a single order until execution.[23] If such an aggregated order matched or improved the Exchange BBO, the aggregated order would be displayed.[24]

CBOE represents that nondisplayed leg orders, including leg orders that were displayed but subsequently become nondisplayed, would remain in the EBook and would be eligible for execution under proposed CBOE Rule 6.53C(c)(iv)(2), but would not be visible in the EBook depth, which, according to CBOE, contains resting orders and quotes not at the BBO.[25]

3. Priority and Execution of Leg Orders; Cancellation and Removal

CBOE represents that the generation of a leg order would not affect the existing priority, or execution opportunities, currently provided to market participants in the regular market in any way.[26] In this regard, CBOE proposes that leg orders (including nondisplayed leg orders) would execute only after all other executable orders and quotes (including any nondisplayed size) at the same price are executed in full and that a leg order may not execute against another leg order.[27] Leg orders at the same price would execute pursuant to the priority and execution rules for complex orders on the COB, except that displayed leg orders would have execution priority over nondisplayed leg orders.[28]

CBOE proposes that when a leg order executes against an incoming order or quote, the other leg(s) of the complex order represented by the leg order would automatically execute against the best-priced resting orders or quotes (other than leg orders) so that the complex order would be executed in full or in a permissible ratio).[29] Prior to the execution of the complex order, any leg orders on the opposite side of the legs of the executing complex order would be canceled.[30] Upon execution of the complex order, any leg orders that represent other legs of the executing complex order would be canceled.[31] According to CBOE, after the complex order executes, new leg orders may be generated to ''replace'' any leg orders representing other complex orders resting on the COB that were canceled as a result of the execution of the complex order, assuming such resting complex orders meet the requirements for the generation of leg orders under

[6] *See* proposed CBOE Rule 6.53(x).

[7] *See* Notice, 78 FR 22928.

[8] *See* proposed CBOE Rule 6.53C(c)(iv)(1).

[9] *See* proposed CBOE Rule 6.53C(c) (iv)(1)(A); Notice, 78 FR 22928, Example A, for an illustration of how leg orders would be generated and priced.

[10] *See* proposed CBOE Rule 6.53C(c)(iv)(1).

[11] *See* Notice, 78 FR 22928, n. 6.

[12] *See* proposed CBOE Rule 6.53C(c)(iv)(1)(C); Notice, 78 FR 22930, Example D for an illustration of the maximum size limit as applied to the generation of leg orders.

[13] *See* proposed CBOE Rule 6.53C(c)(iv)(1).

[14] *See id.*

[15] *See* Notice, 78 FR 22928, n. 5. *See also infra* Section II.C.

[16] *See* Notice, 78 FR 22930, n. 15.

[17] *See* proposed CBOE Rule 6.53C(c)(iv)(1)(A).

[18] *See* proposed CBOE Rule 6.53C, Interpretation and Policy .06.

[19] *See* proposed CBOE Rule 6.53C(c)(iv)(1)(B).

[20] *See* proposed CBOE Rule 6.53C, Interpretation and Policies .12 and proposed CBOE Rule 6.53C(c)(iv)(1)(B).

[21] *See* proposed CBOE Rule 6.53C(c)(iv)(1)(B); Notice, 78 FR 22929–22930, n. 10–11, and Example C for an illustration of this concept.

[22] *See* proposed CBOE Rule 6.53C(c)(iv)(1)(B).

[23] *See* proposed CBOE Rule 6.53C(c)(iv)(1)(C).

[24] *See* Notice, 78 FR 22930, n. 14.

[25] *See* proposed CBOE Rule 6.53C, Interpretation and Policies .12; Notice, 78 FR 22929, Example B, for an illustration of the generation of nondisplayed leg orders.

[26] *See* Notice, 78 FR 22930.

[27] *See* proposed CBOE Rule 6.53C(c)(iv)(2)(A); Notice, 78 FR 22928, n. 6.

[28] *See* proposed CBOE Rule 6.53C(c)(iv)(2)(A).

[29] *See* proposed CBOE Rule 6.53C(c)(iv)(2)(B).

[30] *See id.*

[31] *See* proposed CBOE Rule 6.53C(c)(iv)(2).

CBOE Rule 6.53C(c)(iv)(1).[32] In such an instance, CBOE states that the newly generated leg order(s) would have the same priority as the leg order(s) it replaced with respect to any other leg orders at the same price representing complex orders in the same strategy because the priority of the new leg order(s) (which would be aggregated) would be based on the priority of the complex orders they represent (which would remain unchanged regardless of cancellations of leg orders).[33] If execution of the complex order is partial, CBOE would be able to generate and display leg orders for the remaining size of the complex order assuming the conditions of Rule 6.53C(c)(iv)(1) are satisfied.[34]

CBOE proposes that a leg order would also be canceled if: (1) Execution at the price of the leg order would no longer achieve the net price of the complex order when the other leg(s) executes against the best-priced orders or quotes (other than leg orders); (2) the complex order executes in full or in part against another complex order; or (3) the complex order from which the leg order was generated is canceled or modified.[35] CBOE proposes that a leg order would be removed from display in the EBook if the price of the leg order is no longer at the Exchange BBO or if a complex order in a different strategy generates a larger-sized leg order at the same price.[36] Any leg order that is removed from display in the EBook would be nondisplayed, but would still be eligible for execution.[37]

4. Leg Orders and CBOE Auctions

CBOE proposes to amend certain provisions of CBOE Rule 6.53C, Interpretation and Policies, to provide for how leg orders would interact with the various auction functions available on the Exchange. First, CBOE proposes to amend CBOE Rule 6.53C, Interpretation and Policy .04(b) to provide that if a leg order has been generated for a complex order resting in the COB, the complex order would not be eligible for the automated complex order request for responses (''RFR'') auction process (''COA'').[38] CBOE believes that this provision is appropriate because leg orders would more effectively create opportunities for the execution of complex orders resting in the COB than having those complex orders participate in a COA after the complex order has reached the COB.[39]

Second, CBOE proposes to add CBOE Rule 6.53C, Interpretation and Policy .07 to determine whether CBOE would generate a leg order if a simple order auction [40] is occurring in a leg series at the time that a leg order in that series would otherwise be generated pursuant to CBOE Rule 6.53C(c)(iv). CBOE proposes that:

- If the leg order would be on the same side of the market as the auctioned order with a price worse than the initial auction price of the auctioned order, then the leg order would be generated and the auction would continue.[41]
- If the leg order would be on the same side of the market as the auctioned order with a price equal to or better than the initial auction price of the auctioned order, then no leg order would be generated and the auction would continue. A leg order may later be generated after execution of the auctioned order.[42]
- If the leg order would be on the opposite side of the market as the auctioned order with a price that locks or crosses the initial auction price of the auctioned order, then no leg order would be generated and the auction would continue. A leg order may later be generated after execution of the auctioned order.[43]
- If the leg order would be on the opposite side of the market as the auctioned order with a price that does not lock or cross the initial auction price of the auctioned order, then the leg order would be generated and the auction would continue.[44]

CBOE notes that a leg order would not participate in an auction if a leg order would (a) be displayed in an options series at the time an auction order enters the system and (b) be at the same price as the starting price of the auction order and on the opposite side of the auction order.[45] According to CBOE, the auction order would instead trade with other resting interest at that price and/or any contra order that stopped the auctioned order, while the leg order could continue to be displayed during the auction.[46] According to the Exchange, this result occurs because leg orders only trade after all other executable orders and quotes are executed first.[47]

CBOE believes the proposal would ensure that leg orders would not interact with simple order auctions in order to avoid the system complexities that would result from combining the execution of complex orders with the already complex auction processes.[48] The Exchange believes that market participants would continue to have the same opportunities for execution and potential price improvement through simple order auctions as they would if there were no leg orders present.[49]

B. Amendment No. 2 to the Proposed Rule Change

In Amendment No. 2, the Exchange proposes to make two changes to proposed CBOE Rule 6.53C(c)(iv). First, Amendment No. 2 adds a provision to proposed CBOE Rule 6.53C(c)(iv) to provide that leg orders will only be generated in the minimum increment of the leg series, and the price of a leg order will be rounded down (bid) or up (offer) to the nearest minimum increment if it would otherwise be priced in a smaller increment than the minimum.[50] CBOE represents in Amendment No. 2 that leg orders rounded pursuant to this provision will be ranked, displayed, and eligible to execute with incoming orders at the rounded price. According to Amendment No. 2, a leg order rounded to the nearest increment will function in the same manner as a non-rounded leg order at the rounded increment. Second, Amendment No. 2 eliminates proposed CBOE Rule 6.53C(c)(iv)(2)(C), which governed the interaction of leg orders with all-or-none orders. The Exchange originally proposed that an all-or-none order [51] would only execute against a leg order if it was at least the same size as the all-or-none order and there were no non-leg orders at the Exchange BBO.[52]

[32] *See* Notice, 78 FR 22930, n. 17.

[33] *See id.*

[34] *See* proposed CBOE Rule 6.53C(c)(iv)(2)(B); Notice 78 FR 22931, Example F, for an illustration of a partial execution of a complex order through its leg orders.

[35] CBOE may also cancel a leg order that might trade ahead of a non-leg order against an all-or-none order. *See* proposed CBOE Rule 6.53C(c)(iv)(2)(C).

[36] *See* proposed CBOE Rule 6.53C(c)(iv)(3)(A); Notice 78 FR 22932, Example H for an illustration of cancellation and removal of leg orders generated from complex orders in different strategies.

[37] *See* proposed CBOE Rule 6.53C(c)(iv)(3)(A); Notice 78 FR 22931–22932, Examples G and H, for illustrations of how leg orders are canceled and removed.

[38] *See* proposed CBOE Rule 6.53C, Interpretation and Policy .04.

[39] *See* Notice, 78 FR 22932.

[40] CBOE's simple order auctions include the Hybrid Agency Liaison (''HAL'') auction described in CBOE Rule 6.14A and Automated Improvement Mechanism (''AIM'') auction described in CBOE Rule 6.74A.

[41] *See* proposed CBOE Rule 6.53C, Interpretation and Policy .07(a).

[42] *See* proposed CBOE Rule 6.53C, Interpretation and Policy .07(b).

[43] *See* proposed CBOE Rule 6.53C, Interpretation and Policy .07(c).

[44] *See* proposed CBOE Rule 6.53C, Interpretation and Policy .07(d).

[45] *See* Notice, 78 FR 22933.

[46] *See id.*

[47] *See id.*

[48] *See* Notice, 78 FR 22932.

[49] *See* Notice, 78 FR 22933.

[50] *See* proposed CBOE Rule 6.53C(iv)(1)(A).

[51] *See* CBOE Rule 6.53(i) defining an all-or-none order as: ''a market or limit order which is to be executed in its entirety or not at all.''

[52] *See* proposed CBOE Rule 6.53C(c)(iv)(2)(C).

Under proposed CBOE Rule 6.53C(c)(iv)(2)(C), as originally proposed, if a leg order and a non-leg order(s) were at the Exchange BBO, then the all-or-none order would have either (a) executed against the non-leg order(s) if it was at least the same size as the all-or-none order or (b) the leg order would have been cancelled and the all-or-none order would have been handled pursuant to CBOE's existing rules governing all-or-none orders.[53] Pursuant to CBOE Rule 6.53C(c)(iv)(2)(C), no new leg orders in the applicable options series would have been generated until the all-or-none order was executed or cancelled.[54] As amended, proposed CBOE Rule 6.53(c)(iv)(2)(C) will be eliminated in its entirety and, as a result, a marketable all-or-none order could execute against a leg-order and a non-leg order displayed at the Exchange BBO if such orders were together sufficient to fill the marketable all-or-none order.

C. CBOE Trading System Capacity

CBOE represents that it maintains a rigorous capacity planning program that monitors system performance and projected capacity demands and that, as a general matter, considers the potential system capacity impact of all new initiatives.[55] CBOE represents that it has analyzed the potential impact on system capacity that may result from the proposed rule change and has concluded that the Exchange has sufficient system capacity to handle the generation of leg orders without degrading the performance of its systems or reducing the number of complex order instruments it currently supports.[56] The Exchange represented that it would closely monitor the generation of leg orders and its effect on CBOE's systems, and would carefully manage and curtail the number of leg orders being generated, to ensure that they do not negatively impact system capacity and performance.[57]

III. Discussion

After careful review, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1 and 2, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[58] In particular, the Commission finds that the proposed rule change, as amended, is consistent with Section 6(b)(5) of the Act,[59] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes that leg orders could facilitate the execution of complex orders resting on CBOE's COB by increasing the opportunities for eligible complex orders to execute against interest in the leg market on CBOE's EBook, thereby benefitting investors seeking to execute complex orders. In addition, the Commission believes that leg orders could benefit participants in the leg market by providing additional liquidity, and potentially more favorable executions, for leg market interest. The Commission notes that it previously approved proposals by other options exchanges to implement leg orders.[60]

Leg orders will be firm orders that represent one leg of a non-contingent complex order resting on the COB if the ratio of that leg to the other legs of the complex order is equal to or can be reduced to one.[61] The Commission notes that, on CBOE, leg orders will only be generated in the minimum increment of the leg series, and the price of the leg order will be rounded down (bid) or up (offer) to the nearest minimum increment if it would otherwise be priced in a smaller increment than the minimum.[62] As noted above, the Exchange represents that a leg order rounded to the nearest increment will be ranked, displayed, and eligible to execute with incoming orders at the rounded price and that rounded leg orders will function in the same manner as non-rounded leg orders.[63] Under CBOE's proposal, leg orders will not be generated if the price of the leg order would lock or cross the NBBO.[64]

The Commission notes that a leg order will be executed only after all other executable orders and quotes (including any nondisplayed size of any non-leg orders) at the same price are executed in full and that a leg order may not execute against another leg order.[65] Accordingly, CBOE represents that the generation of a leg order would not affect the existing priority, or execution opportunities, currently provided to market participants in the regular market in any way.[66]

The Commission notes that the proposal provides for when a leg order will be displayed and when it would be nondisplayed. The Exchange represents that nondisplayed leg orders will function in the same manner as displayed leg orders except that displayed leg orders will have priority over nondisplayed leg orders.[67]

As noted above, CBOE represents that it will carefully manage and curtail the number of leg orders being generated so that they do not negatively impact system capacity and performance.[68] CBOE represents, further, that it will curtail the number of leg orders on an objective basis, such as by limiting the number of leg orders generated in a particular class, and that it will not limit the generation of leg orders on the basis of the entering participant or the participant category of the order (*i.e.,* professional, professional customer, or public customer).[69]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 2 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2013–026 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission,

[53] *See id. See generally* CBOE Rule 6.44 Interpretations and Policies .01–.03.

[54] *See* proposed CBOE Rule 6.53C(c)(iv)(2)(C).

[55] *See* Notice, 78 FR 22933.

[56] *See id.*

[57] *See id.*

[58] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[59] 15 U.S.C. 78f(b)(5).

[60] *See* Securities Exchange Act Release Nos. 66234 (January 25, 2012), 77 FR 4852 (January 31, 2012) (order approving File No. SR–ISE–2011–82) and 69419 (April 19, 2013), 78 FR 24449 (April 25, 2013) (order approving File No. SR–BOX–2013–01).

[61] *See supra* Section II.A.

[62] *See* proposed CBOE Rule 6.53C(iv)(1)(A). *See also supra* Section II.B.

[63] *See supra* Section II.B.

[64] *See* proposed CBOE Rule 6.53C(c)(iv)(1)(A). *See also supra* note 17 and accompanying text.

[65] *See* proposed CBOE Rule 6.53C(c)(iv)(2)(A); Notice, 78 FR 22928, n. 6. *See also supra* notes 27 and 46 and accompanying text.

[66] *See* Notice, 78 FR 22930. *See also infra* note 26 and accompanying text.

[67] *See* Notice, 78 FR 22929.

[68] *See supra* Section II.C.

[69] *See* Notice, 78 FR 22930, n. 15.

100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2013–026. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2013–026, and should be submitted on or before August 9, 2013.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 2

The Commission finds good cause for approving the proposed rule change, as amended by Amendment No. 2, prior to the 30th day after the date of publication of notice in the **Federal Register**. Amendment No. 2 revises the proposal, to, among other things, eliminate proposed CBOE Rule 6.53C(c)(iv)(2)(C) in its entirety because the provision would be inconsistent with Section 11A of the Act[70] and Rule 602(a) of Regulation NMS (''Quote Rule'').[71] For this reason, the Commission finds good cause for approving the proposed rule change, as amended, on an accelerated basis, pursuant to Section 19(b)(2) of the Act.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[72] that the proposed rule change (SR–CBOE–2013–26), as amended, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[73]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–17312 Filed 7–18–13; 8:45 am]

BILLING CODE 8011–01–P

[70] 15 U.S.C. 78k–1.

[71] 17 CFR 242.602(a). *See* 17 CFR 242.602(a)(1)(i).

[72] 15 U.S.C. 78s(b)(2).

[73] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 8384]

Privacy Act; System of Records: Human Resources Records, State–31

SUMMARY: Notice is hereby given that the Department of State proposes to amend an existing system of records, Human Resources Records, State–31, pursuant to the provisions of the Privacy Act of 1974, as amended (5 U.S.C. 552a) and Office of Management and Budget Circular No. A–130, Appendix I.

DATES: This system of records will be effective on August 28, 2013, unless we receive comments that will result in a contrary determination.

ADDRESSES: Any persons interested in commenting on the amended system of records may do so by writing to the Director; Office of Information Programs and Services, A/GIS/IPS, Department of State, SA–2, 515 22nd Street NW., Washington, DC 20522–8001.

FOR FURTHER INFORMATION CONTACT: Director; Office of Information Programs and Services, A/GIS/IPS, Department of State, SA–2, 515 22nd Street NW., Washington, DC 20522–8001.

SUPPLEMENTARY INFORMATION: The Department of State proposes that the current system will retain the name ''Human Resources Records'' (previously published as 65 FR 69359). The information collected and maintained in this system is in keeping with the Department's mission to document all processes associated with individual employment histories and career progression; to ensure that all employees and potential employees have equal opportunities; and to make personnel management determinations about employees throughout their Federal careers. The proposed system will include administration updates and modifications to the following sections: Categories of individuals, Categories of records, Routine uses, and Safeguards.

The Department's report was filed with the Office of Management and Budget. The amended system description, ''Human Resources Records, State–31,'' will read as set forth below.

Joyce A. Barr,

Assistant Secretary for Administration, U.S. Department of State.

STATE–31

SYSTEM NAME:

Human Resources Records.

SECURITY CLASSIFICATION:

Classified and unclassified.

SYSTEM LOCATION:

Department of State, 2201 C Street NW., Washington, DC 20520; State Annex 01, 2401 E Street NW., Washington, DC 20037; State Annex 03, 2121 Virginia Avenue NW., Washington, DC 20037; State Annex 44, 301 4th Street SW., Washington, DC 20547; overseas at U.S. embassies, U.S. consulates general, and U.S. consulates; U.S. missions; and the National Personnel Records Center, 111 Winnebago Street, St. Louis, MO 63118.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All applicants for employment with the Department of State (including unsuccessful applicants); all current and former Civil Service (CS) and Foreign Service (FS) employees of the Department of State including members of the Senior Executive Service (SES), Presidential Appointees, employees under full-time, part-time, intermittent, temporary, and limited appointments; anyone serving in an advisory capacity (compensated and uncompensated); other agency employees on detail to the Department of State; former Foreign Service Reserve Officers; student applicants for internships, Presidential Management Fellows, Foreign Affairs Fellowship Program Fellows, student interns and other student summer hires, Stay-in-School student employees, and Cooperative Education Program participants; and prospective alien spouses and cohabitants of Department of State employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records may include identifying information, such as, but not limited to, name, date of birth, home address, mailing and email addresses, numeric identifier (such as employee identification number, SGID, or Social Security number) and telephone numbers. Types of files include

documents relating to class action lawsuits, annuitants under the Foreign Service Retirement and Disability System and the Foreign Service Pension System as well as Civil Service annuitants, prospective alien spouses and cohabitants of Department employees, employees who apply for their spouses or children to be expeditiously naturalized, employees detailed or seconded to international organizations, Foreign Service personnel separated for cause; official personnel files; documents relating to merit promotions, recruitment and employment, employee relations, career development and counseling, performance, conduct, suitability, and discipline, Foreign Service promotion and Permanent Change of Station (PCS) travel. These records may contain any documents not otherwise stated relating to employment, to include, but not limited to, hiring, employment and separation from the Department.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

22 U.S.C. 2581 (General Authority of Secretary of State); 22 U.S.C. 2651a (Organization of the Department of State); 22 U.S.C. 3901 et seq. (Foreign Service Act of 1980); 22 U.S.C. 3921 (Management of the Foreign Service); 22 U.S.C. 4041 (Administration of the Foreign Service Retirement and Disability System); 5 U.S.C. 301–302 (Management of Executive Departments); Executive Order 9397, as amended (Numbering System for Federal Accounts Relating to Individual Persons); Executive Order 9830 (Amending the Civil Service Rules and Providing for Federal Personnel Administration); and Executive Order 12107 (Relating to the Civil Service Commission and Labor-Management in the Federal Service) and successor authorities.

PURPOSE:

The information collected and maintained in this system is in keeping with the Department's mission to document all processes associated with individual employment histories and career progression; to ensure that all employees and potential employees have equal opportunities; and to make personnel management determinations about employees throughout their Federal careers.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The information in Human Resources Records may be shared:

A. With consulting services that provide information about available aids, devices and methods of accommodating employees with disabilities;

B. With the Office of Personnel Management for its government-wide personnel management functions such as pay, benefits, and retirement deductions or other relevant personnel processes;

C. With other Federal agencies, state governments, foreign governments and international organizations where employees are being considered for detail, assignment or secondment;

D. With academic institutions to which Department employees may be assigned for long-term training;

E. With any member of an agency's Performance Review Board or other panel when the member is not an official of the employing agency. Information would then be used for approving or recommending selection of candidates for Executive development or Senior Executive Service (SES) candidate programs, issuing a performance rating of record, issuing performance awards, nominating for meritorious and distinguished executive ranks, removal, reduction in grade, and other personnel actions based on performance;

F. With attorneys, union representatives or other persons designated by employees in writing to represent them in complaints, grievance, appeal, or litigation cases;

G. With requestors in determining a former spouse's entitlement to benefits and other inquiries related to retirement benefits;

H. With the President of the United States, the Executive Office of the President and legislative and appropriations committees of the U.S. Congress charged with consideration of legislation and appropriations for the Foreign Service, or representatives duly authorized by such committees;

I. With labor organization officials when such information is relevant to personnel policies affecting employment conditions and necessary for exclusive representation by the labor organization;

J. With officials of foreign governments and other U.S. government agencies for clearance before a Federal employee is assigned to that country as well as for the procurement of necessary services for American personnel assigned overseas, such as permits of free entry and identity cards;

K. With the Department of Labor, Department of Veterans Affairs, Social Security Administration, Department of Defense, or any other Federal agencies that have special civilian employee retirement and disability programs; or to a national, state, county, municipal, or other publicly recognized income administration agency (e.g. State unemployment compensation agencies), when necessary to adjudicate a claim under the retirement, insurance, unemployment or health benefits programs of the Department or an agency cited above, or to an agency to conduct an analytical study or audit of benefits being paid under such programs;

L. With the Office of Federal Employees Group Life Insurance, information necessary to verify election, declination, or waiver of regular and/or optional life insurance coverage, or eligibility for payment of a claim for life insurance;

M. With health insurance carriers contracting with the Federal government to provide a health benefits plan under the Federal Employees Health Benefits Program, information necessary to identify enrollment in a plan, to verify eligibility for payment of a claim for health benefits, or to carry out the coordination or audit of benefit provisions of such contracts;

N. With any person who is responsible for the care of an individual to whom a record pertains who is mentally incompetent or under other legal disability. Information in the individual's record may be disclosed to said person to the extent necessary to assure payment of benefits to which the individual is entitled;

O. With public and private organizations, including news media, which grant or publicize employee recognition to consider and select employees for incentive awards and other honors and to publicize awards and honors granted;

P. With the Department of Justice in connection with proceedings before a court, adjudicative body, or other administrative body when any of the following is a party to litigation or has an interest in such litigation and the Department of State determines that the use of such records is arguably relevant and necessary to the litigation of (1) the Department of State or any component thereof, (2) any employee of the Department of State in his or her official capacity, (3) any employee of the Department of State in his or her individual capacity where the Department of Justice or the Department of State has agreed to represent the employee, or (4) the United States, when the Department of State determines that litigation is likely to affect the Department of State or any of its components;

Q. To implement court decisions and/or terms of settlement agreements reached by the parties;

R. To prepare reports to the courts in compliance with monitoring requirements;

S. In response to an order from a court or an administrative body directing the production of personnel records (including, but not limited to the Equal Employment Opportunity Commission, the Foreign Service Grievance Board and the Merit Systems Protection Board);

T. With other Government agencies and private organizations, institutions or individuals to verify employment, to process security clearances and to request record or credit checks;

U. To provide an official of another Federal agency information needed in the performance of official duties in support of the functions for which the records were collected and maintained;

V. To disclose information to Equal Employment Opportunity (EEO) counselors and EEO investigators in connection with EEO complaints and to the Equal Employment Opportunity Commission when requested in connection with investigations of alleged or possible discrimination practices in the Federal sector, examination of Federal affirmative employment programs, compliance by Federal agencies with the Uniform Guidelines on Employee Selection Procedures, or other functions vested in the Commission;

W. With the Department of Labor's Office of Workers' Compensation programs relating to benefits under the Federal Employees Compensation Act; and

X. To disclose information to the news media and the public when a matter involving the Department of State has become public knowledge; the Under Secretary for Management determines that in response to the matter in the public domain, disclosure is necessary to provide an accurate factual record on the matter; and the Under Secretary for Management determines that there is a legitimate public interest in the information disclosed.

The Department of State periodically publishes in the **Federal Register** its Prefatory Statement of Routine Uses which applies to all of its Privacy Act systems of records. These standard routine uses apply to Human Resources Records, State–31.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic media and hard copy.

RETRIEVABILITY:

By an individual name and numeric identifier.

SAFEGUARDS:

All users are given cyber security awareness training which covers the procedures for handling Sensitive but Unclassified information, including personally identifiable information (PII). Annual refresher training is mandatory. In addition, all Foreign Service and Civil Service employees and those Locally Engaged Staff who handle PII are required to take the Foreign Service Institute distance learning course, PA 459, instructing employees on privacy and security requirements, including the rules of behavior for handling PII and the potential consequences if it is handled improperly. Before being granted access to Human Resources Records, a user must first be granted access to the Department of State computer system.

Remote access to the Department of State network from non-Department owned systems is authorized only to unclassified systems and only through a Department approved access program. Remote access to the network is configured with the Office of Management and Budget Memorandum M–07–16 security requirements which include, but are not limited to, two-factor authentication and time out function.

All Department of State employees and contractors with authorized access have undergone a thorough background security investigation. Access to the Department of State, its annexes and posts abroad is controlled by security guards and admission is limited to those individuals possessing a valid identification card or individuals under proper escort. All paper records containing personal information are maintained in secured file cabinets in restricted areas, access to which is limited to authorized personnel only. Access to computerized files is password-protected and under the direct supervision of the system manager. The system manager has the capability of printing audit trails of access from the computer media, thereby permitting regular and ad hoc monitoring of computer usage. When it is determined that a user no longer needs access, the user account is disabled.

RETENTION AND DISPOSAL:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with published records schedules of the Department of State and as approved by the National Archives and Records Administration. More specified information may be obtained by writing to the Director, Office of Information Programs and Services, A/GIS/IPS, SA–2, Department of State, 515 22nd Street NW., Washington, DC 20522–8100.

SYSTEM MANAGER(S) AND ADDRESS:

The Director General of the Foreign Service and Director of Human Resources, Department of State; 2201 C Street NW., Washington, DC 20520.

NOTIFICATION PROCEDURE:

Individuals who have reason to believe that the Bureau of Human Resources might have records pertaining to themselves should write to the Director; Office of Information Programs and Services, A/GIS/IPS; SA–2, Department of State; 515 22nd Street NW., Washington, DC 20522–8100. The individual must specify that he or she wishes the Human Resources Records to be checked. At a minimum, the individuals must include: name; date and place of birth; approximate dates of employment with the Department of State or when in process for a potential appointment; current mailing address and zip code; signature; and other information helpful in identifying the record.

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to or amend records pertaining to themselves should write to the Director; Office of Information Programs and Services (address above).

CONTESTING RECORD PROCEDURES:

(See above.)

RECORD SOURCE CATEGORIES:

These records contain information obtained directly from the individual who is the subject of these records, previous employers, supervisors, Foreign Service inspectors, any/all offices within the Bureau of Human Resources (counselors, placement officers, and personnel technicians), other bureaus (administrative/executive officers, personnel and payroll offices, security, medical, and legal), reports of the Board of Examiners of the Foreign Service, Foreign Service Employee Evaluation Reports and Selection Board findings, the Foreign Service Institute, colleges, universities, Armed Forces academic institutions, contractors

responsible for administration of the Foreign Service written examination, and other authorized agencies administering pre-employment tests, Office of Personnel Management and other Federal agencies, prospective alien spouses of Foreign Service employees; grievance staff and appeals boards, affidavits and testimony of witnesses.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

Pursuant to 5 U.S.C. 552a (k)(1), subject to the provisions of section 552(b)(1), records are exempted from 5 U.S.C. 552a (c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f) to protect material required to be kept Secret. Pursuant to 5 U.S.C. 552a (k)(4), records contained within this system that are maintained solely for statistical purposes are also exempted from 5 U.S.C. 552a (c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f). Pursuant to 5 U.S.C. 552a (k)(5) and (k)(7), certain records contained within this system contain confidential source information and are exempted from 5 U.S.C. 552a (c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f). Pursuant to 5 U.S.C. 552a (k)(6), records that contain testing or examination material the release of which may compromise testing or examination procedures are also exempted from 5 U.S.C. 552a (c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f). See Department of State Rules published in 22 CFR 171.

[FR Doc. 2013–17391 Filed 7–18–13; 8:45 am]

BILLING CODE 4710–26–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

Transportation Infrastructure Financing and Innovation Act (TIFIA) Program; Agency Information Collection Activities and Request for Comments

AGENCY: Office of the Secretary of Transportation (OST).

SUMMARY: The Department of Transportation (DOT) invites public comments on a request to the Office of Management and Budget (OMB) to approve an Emergency Information Collection Request in accordance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 USC 3501 *et seq*). This request is being submitted to OMB via an Emergency Information Collection Request.

On July 6, 2012, the President of the United States signed the Moving Ahead for Progress in the 21st Century Act of 2012 (MAP–21). MAP–21 authorized $750 million in FY 2013 and $1 billion in FY 2014 for the Transportation Infrastructure Financing and Innovation Act (TIFIA) program to pay the subsidy cost of supporting Federal credit. The TIFIA program will provide Federal credit assistance in the form of direct loans, loan guarantees, and standby lines of credit to eligible surface transportation projects. This information collection relates to the collection of information from entities interested in TIFIA credit assistance and assists the DOT in evaluating projects and project sponsors for program eligibility and creditworthiness.

DATES: Written comments should be submitted by August 5, 2013.

ADDRESSES: Comments are invited on: (a) The need for the proposed collection of information for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques. You may submit comments identified by Docket No. DOT–OST–2013–0138 through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: The TIFIA program manager via email at *TIFIACredit@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Transportation Infrastructure Financing and Innovation Act program or TIFIA program.

OMB Control Number: 2105–New.

Affected Public: State and local governments, transit agencies, railroad companies, special authorities, special districts, and private entities.

Estimated Total Annual Number of Responses: 50 letters of interest and 50 applications.

Estimated Total Annual Burden Hours: 6,000 hours. Based on the number and type of interested stakeholders that have contacted the Department about this program, OST estimates that it will receive 50 applications and letters of interest and that it will generally not take applicants more than 100 person-hours to assemble individual applications and 20 person-hours to assemble individual letters of interest. Therefore, the total annual hour burden of this collection of applications is 6,000 hours.

Frequency of Collection: The Department expects that this information collection will occur on a rolling basis as interested entities seek TIFIA credit assistance.

Background: This is an existing information collection without an OMB Control Number. DOT has published a notice in the **Federal Register** (also available at: *http://www.fhwa.dot.gov/ipd/pdfs/tifia/fy2013_tifia_nofa_073112.pdf*) to give project sponsors an opportunity to submit Letters of Interest and applications for the newly authorized funding as soon as possible. However, in addition to authorizing more funding for TIFIA credit assistance, MAP–21 made some significant changes to the TIFIA program's structure, including the terms and conditions pursuant to which DOT can provide TIFIA credit assistance. DOT is required to solicit letters of interest and applications for TIFIA credit assistance from interested applicants. DOT has developed forms that provide a way for interested applicants to submit information required by DOT in order for DOT to evaluate that interested applicant's application for TIFIA credit assistance. The forms for the letter of interest and application are available for review at *http://www.fhwa.dot.gov/ipd/tifia/guidance_applications/tifia_applications.htm.* The DOT will use the collected information to evaluate and select recipients for credit assistance as authorized under MAP–21. Applicants may be asked to provide additional supporting evidence or to quantify details during the review and negotiation process on a case-by-case basis, but completion of the letter of interest and application.

MAP–21 establishes a multi-step application process for TIFIA credit assistance. This process begins with the submission of a Letter of Interest and determination of eligibility. Only after a project sponsor has submitted a Letter of Interest and met all statutory eligibility requirements will the project sponsor be invited to submit an application.

The Letter of Interest must (i) describe the project and the location, purpose, and cost of the project, (ii) outline the proposed financial plan, including the requested credit assistance and the proposed obligor, (iii) provide a status of environmental review, and (iv) provide information regarding satisfaction of other eligibility requirements of the TIFIA credit program. Letters of Interest will be submitted using the form on the TIFIA Web site: *http://www.fhwa.dot.gov/ipd/tifia/guidance_applications/index.htm.* DOT has revised the form for the Letter of Interest to reflect changes made to the TIFIA program by MAP–21. The Letter of Interest form requires project sponsors to provide information demonstrating satisfaction (or expected satisfaction if permitted by the statute) of each of the eligibility requirements included in MAP–21. DOT estimates that the letter of interest would require approximately 20 hours in each instance to complete.

If a project sponsor is invited to submit an application, DOT estimates that each application will require approximately 100 hours to complete. The information that DOT seeks through the application includes: Contact information for the applicant entity; project information including name, location, description, rural project description (if applicable), purpose (quantitative/qualitative details), cost and TIFIA credit assistance request, project management and compliance monitoring plan, maintenance and operations plan, satisfaction of eligibility requirements including creditworthiness (rate covenant, coverage requirements, investment grade rating(s)), fostering partnerships that attract public and private investment, how TIFIA assistance would enable the project to proceed at an earlier date or with reduced lifecycle costs, how TIFIA assistance would reduce the contribution of federal grant assistance, environmental review (NEPA), permits and approvals, transportation planning and programming process approvals (STIP and TIP), construction contracting process readiness, project schedule, a financial plan including estimated capital project cost, amount and type of credit assistance requested, amount of TIFIA assistance requested, a summary table: Detailing sources and uses of funds, cash flow pro forma, a supplementary narrative detailing other borrowed funds and revenue sources (including pledged repayment source), proposed terms for the requested TIFIA credit instrument, reasons for selecting the proposed type(s) of credit instrument, flexibility in financial plan to support a reduced percentage-share of TIFIA credit assistance, risks and mitigation strategies, details on the applicant's organizational structure, including background information and legal authority, organization and management, identity of the entity that will serve as applicant (public-sector agency or private-sector firm), whether the applicant the same entity as the borrower (detail project team members), prior experience, financial condition, and litigation and/or conflicts.

Issued in Washington, DC on July 16, 2013.

Patricia Lawton,

Departmental PRA Clearance Officer, Office of the Secretary.

[FR Doc. 2013–17406 Filed 7–18–13; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

Use of Wireless Mobile Data Devices as Transponders for the Commercial Motor Vehicle Information Systems and Networks (CVISN) Electronic Screening Systems

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice; announcement of policy.

SUMMARY: FMCSA announces that Commercial Mobile Radio Services (CMRS) network devices can be used as transponders for the purposes of CVISN electronic screening truck inspection and weigh station bypass systems. CMRS network devices such as smartphones, tablets, fleet management systems, global positioning system (GPS) navigational units, and onboard telematics devices (referred to collectively as ''wireless mobile data devices'') have the capability of transmitting and receiving the same information between the driver and the inspection site as the dedicated short-range communication (DSRC)-enabled transponders operating at the 915 MHz frequency currently used to fulfill the CVISN electronic screening requirement for core compliance. This policy does not affect the applicability or enforcement of FMCSA's regulations prohibiting texting and the use of hand-held wireless mobile phones by commercial motor vehicle (CMV) drivers.

FOR FURTHER INFORMATION CONTACT: For information concerning this notice or this activity, contact Mr. Jose M. Rodriguez, CVISN Technical Program Manager, Technology Division of FMCSA, (202) 366–3517, *jose.rodriguez@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

The purpose of the CVISN program is to advance technological capability and promote the deployment of Intelligent Transportation System applications for commercial vehicle operations, including commercial vehicle, commercial driver, and carrier specific information systems and networks. CVISN is divided into core and expanded deployment. Before a State is eligible for expanded deployment funding, it must complete core deployment. In order to complete core deployment, States must install an electronic system to screen transponder-equipped commercial vehicles at a minimum of one fixed or mobile inspection site in the State and replicate this screening at other sites. The objective of electronic screening is to identify enrolled vehicles; to screen vehicles based on safety history, weight, and credential status (e.g., registration, fuel tax payment, operating authority); and to allow enrolled vehicles that meet the State's criteria to bypass inspection sites. By allowing compliant vehicles to bypass weigh stations and inspection sites without stopping, FMCSA and its State partners are able to increase the effectiveness of enforcement efforts by targeting high risk motor carriers. Currently, weigh stations and inspection sites electronically screen DSRC-enabled transponder-equipped CMVs to determine if an inspection is necessary or if the driver should bypass the weigh station or inspection site.

In the past, States have installed only DSRC electronic screening transponder systems to satisfy the CVISN core electronic screening requirement because that was the prevalent technology at the time the CVISN program was authorized. States or private companies providing the DSRC screening services were required to install DSRC infrastructure to participate in the information sharing between roadside activities and the vehicles required to be in compliance with Core CVISN deployment. States may continue to deploy DSRC electronic screening transponder systems operating at the 915 MHz frequency to fulfill the CVISN electronic screening requirement for core compliance.

Use of CMRS To Comply With CVISN

Since the CVISN program began, there has been a significant expansion of CMRS networks in North America.

States may now use available CMRS networks to screen trucks equipped with wireless mobile data devices used as transponders. CMRS network devices such as smartphones, tablets, fleet management systems, GPS navigational units, and onboard telematics devices are capable of transmitting and receiving multiple forms of wireless mobile data and thus, are considered transponders for the purposes of the CVISN program.

CMRS transponders use commercially available mobile radio transmission frequencies to access cellular data networks and exchange carrier and vehicle credentials utilizing web-based technologies. Triggered via GPS signaling, CMRS transponders communicate through the internet to electronic screening systems that issue traditional red light/green light responses for in-cab displays mounted on the dashboard. Because CMRS transponders are hardware neutral, drivers can install a variety of cellular-enabled GPS-connected devices (such as smartphones, tablets, fleet management systems, GPS navigational units, and onboard telematics devices) in vehicles.

This policy announcement does not affect the applicability or enforcement of FMCSA's regulations under 49 CFR part 392 prohibiting texting and the use of hand-held wireless mobile phones by commercial motor vehicle (CMV) drivers.

Benefits

Use of wireless mobile data devices as transponders with CMRS provides benefits to FMCSA and key stakeholders including State CMV enforcement agencies, industry, and participating motor carriers:

1. All of the remaining 11 States that have not yet achieved CVISN core deployment status because they have not met the CVISN electronic screening requirement will have another option to achieve CVISN core deployment status. This makes States eligible for the expanded CVISN funding deployment milestone and improves data sharing among States and FMCSA.

2. The electronic screening system enables State enforcement agencies to identify CMV drivers and check their safety status at highway speeds and enables FMCSA and State partners to more efficiently utilize resources to target high risk carriers.

3. The capability to check the safety status of drivers and vehicles at highway speeds will decrease congestion and vehicle emissions at inspection sites. Motor carriers will avoid fuel costs associated with idling at weigh stations and inspection sites.

4. State agencies can add additional electronic screening sites, both fixed and mobile, with no infrastructure-related costs. CMRS-enabled systems give States significant flexibility in activating and de-activating geofences (the virtual perimeter for the real-world geographic area in which truck station bypass systems electronically screen CMVs).

5. For participating motor carriers, available CMRS-based electronic screening systems are technology-platform neutral and could be operated, on wireless mobile data devices, as well as onboard fleet management systems. The use of the system is consistent with FMCSA's prohibition against the use of hand-held mobile phones and texting and complements existing DSRC-based screening systems.

Issued on: July 8, 2013.

Anne S. Ferro,

Administrator.

[FR Doc. 2013–17418 Filed 7–18–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2013–0124, Notice No. 13–7]

Paperless Hazard Communications Pilot Program

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: PHMSA invites volunteers for a pilot program to evaluate the effectiveness of paperless hazard communications systems and comments on an information collection activity associated with the pilot program. ''Moving Ahead for Progress in the 21st Century Act'' (MAP–21) authorizes PHMSA to conduct a pilot program to evaluate the feasibility and effectiveness of using paperless hazard communications systems. In accordance with MAP–21, in conducting the pilot projects, PHMSA may not waive the current shipping paper requirements. In addition, MAP–21 indicates that PHMSA must consult with organizations representing fire and other emergency responders, law enforcement, and regulated entities. Upon completion of the pilot projects, PHMSA must evaluate the feasibility and effectiveness of paperless hazard communications systems and make a recommendation to Congress regarding regulatory changes that would permanently authorize the use of paperless hazard communications systems. The report is due to Congress by October 1, 2014. The intent of this notice is to: (1) Describe the current regulatory requirements for shipping papers; (2) describe authority granted under MAP–21; (3) explain the goal, scope, and intent of the pilot program; (4) seek volunteers to participate in the pilot projects and describe criteria for selecting pilot participants from the volunteers; and (5) seek comment on the request for information to be collected in conducting the pilot projects and in consulting with organizations representing fire and other emergency responders, law enforcement, and regulated entities. Information gathered will enable PHMSA to generate a report to Congress detailing: (1) The performance of each paperless hazard communications system tested during the pilot projects; (2) PHMSA's assessment of the safety and security impacts on stakeholders; (3) the associated costs and benefits; and (4) PHMSA's regulatory recommendation(s).

DATES: Interested persons are invited to submit comments on or before September 17, 2013.

ADDRESSES: You may submit comments, and statements of interest to volunteer, identified by the docket number (PHMSA–2013–0124) by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *FAX:* 1–202–493–2251.
- *Mail:* Docket Management System, U.S. Department of Transportation, Docket Operations, Routing Symbol M–30, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Docket Operations, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, from 9:00 a.m. to 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and docket number for this notice at the beginning of the comment. To avoid duplication, please use only one of these four methods. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you provide.

Docket: For access to the dockets to read background documents or comments received, go to *http://www.regulations.gov* or DOT's Docket Operations Office (see **ADDRESSES**).

Privacy Act: Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477) or you may visit *http://www.gpo.gov/fdsys/pkg/FR-2000-04-11/pdf/00-8505.pdf*

FOR FURTHER INFORMATION CONTACT: James O. Simmons, U.S. Department of Transportation, Engineering and Research Division (PHH–23), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., East Building, 2nd Floor, Washington, DC 20590–0001, Telephone (202) 366–4545. Requests for a copy of the information collection should be directed to T. Glenn Foster, U.S. Department of Transportation, Standards and Rulemaking Division (PHH–12), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., East Building, 2nd Floor, Washington, DC 20590–0001, Telephone (202) 366–8553.

SUPPLEMENTARY INFORMATION: Section 1320.8 (d), Title 5, Code of Federal Regulations (CFR) requires that PHMSA provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies an information collection activity PHMSA is undertaking to evaluate the effectiveness of a paperless hazard communications pilot program authorized under Title III, Section 33005, of the Hazardous Materials Transportation Safety Improvement Act of 2012 (H.R. 4348), also referenced as the ''Moving Ahead for Progress in the 21st Century Act'' (H.R. 4348, ''MAP–21''). This notice also seeks volunteers (shippers, carriers, law enforcement, and emergency response personnel) who are interested in participating in the pilot projects. The pilot projects and the information collection activity identified in this notice have been designed to ensure full collaboration with modal administrations, law enforcement personnel, fire services and emergency response providers, and regulated entities (shippers and carriers who transport hazardous materials by air, highway, rail, and water) to test the feasibility and then evaluate both the feasibility and effectiveness of using paperless hazardous materials (e-HM) communications systems (e-systems). The following sections describe the: (1) Current regulatory requirements for shipping papers; (2) authority granted under MAP–21; (3) goal, scope, and intent of the pilot program and request for volunteers to participate in the pilots; (4) criteria used for selecting pilot participants; and (5) request for information to be collected in conducting the pilot projects and in consulting with organizations representing fire and other emergency responders, law enforcement, and regulated entities.

1. History of and Current Regulatory Requirements for Shipping Papers

The Hazardous Materials Regulations (HMR; 49 CFR Parts 171–180) require a person who offers hazardous materials for transportation in commerce to describe the hazardous materials on a shipping paper in the manner required in 49 CFR Part 172, Subpart C. The shipping paper requirements identify key hazard communication information (e.g., UN number, proper shipping name, hazard class, packing group, type and quantity of packaging, and emergency response telephone number). Unless an exception from the shipping paper requirements is provided in the regulations, a paper copy of the shipping paper must accompany a hazardous material during transportation. A shipping paper includes ''a shipping order, bill of lading, manifest or other shipping document serving a similar purpose and containing the information required by §§ 172.202, 172.203, and 172.204'' (49 CFR 171.8, definition of ''shipping paper''). A hazardous waste manifest ''may be used as the shipping paper'' if it contains all the information required by Part 172, Subpart C (49 CFR 172.205(h)).

In 1994, Congress amended the Federal hazardous materials transportation law (Federal hazmat law) to require that, after a hazardous material ''is no longer in transportation,'' all offerors and carriers of a hazardous material must retain the shipping paper ''or *electronic image* thereof for a period of 1 year to be accessible through their respective principal places of business'' (49 U.S.C. 5110(e), added by Pub. L. 103–311, Title I, § 115, 108 Stat. 1678 (Aug. 26, 1994)). That section also requires that the offeror and carrier ''shall, upon request, make the shipping paper available to a Federal, State, or local government agency at reasonable times and locations.''

On September 12, 2001, the Research and Special Programs Administration (the predecessor to PHMSA) issued a notice of proposed rulemaking (NPRM) to amend the HMR to conform with § 5110(e) (66 FR 47443). The 2001 NPRM indicated an *electronic image* includes an image transmitted by a facsimile (FAX) machine, an image on the screen of a computer, or an image generated by an optical imaging machine. To facilitate compliance with, and enforcement of, the hazardous materials shipping paper requirement, in 2002 PHMSA further amended the HMR regarding the retention and information requirements associated with shipping papers. Amendments included extending the retention period to 375 days; requiring the copy to include the date that the shipment is accepted for transportation by the initial carrier; and requiring that the shipping paper copy or its *electronic image* be accessible at or through the principal place of business of each person required to prepare or maintain it during transportation. Consideration for allowing the use of electronic communication while hazardous materials are actually in transportation is the next step in the evolution of hazard communication.

The implementation of e-systems has already begun and will evolve if industry determines that investing in technology is economically beneficial for its businesses. Spurred by competitive demands, just-in-time delivery requirements, and the globalization of supply chains, many transportation and logistics industries have embraced modern innovations to communicate. However, the HMR requires the use of a paper copy of the shipping document. The rationale behind a paper-based system is to convey the necessary information in a consistent manner that is widely understood and accepted by all regulated entities, law enforcement, and emergency responders.

2. Authority Granted Under MAP–21

Section 33005 of MAP–21 provided PHMSA the authority to conduct paperless hazard communications pilot projects. PHMSA will conduct the pilot projects to evaluate the feasibility of using e-systems to convey the same information that is contained on a paper copy of a shipping document. MAP–21, Section 33005 states that PHMSA: (1) Cannot waive the current statutory shipping paper requirements, and (2) must consult with organizations representing fire and other emergency responders, law enforcement, and regulated entities. In addition, at least one pilot project must take place in a rural area.

Upon completion of the pilot projects, PHMSA must prepare a report that provides: (1) A detailed description of the pilot projects; (2) an evaluation of each pilot project to include an evaluation of the performance of the e-systems; (3) an assessment of the safety and security impacts of using e-systems to include the impact on the public, emergency responders, law enforcement, and on conducting inspections and investigations; (4) an analysis of the associated benefits and costs of using e-systems for each mode of transportation; and (5) a recommendation whether e-systems should be permanently incorporated into the Federal hazmat regulations. The Secretary shall submit the report to the Committee on Commerce, Science, and Transportation of the U.S. Senate and to the Committee on Transportation and Infrastructure of the U.S. House of Representatives by October 2014, two years after the enactment of the Hazardous Materials Transportation Safety Improvement Act of 2012.

3. Goal, Scope, and Intent of the Pilot Program and Request for Volunteers To Participate in the Pilot Projects

Beginning in 2007, PHMSA initiated actions to implement paperless hazard communications. PHMSA has conducted activities including: (1) Building a cooperative effort between transportation entities and regulatory agencies; (2) publishing a notice on the use of electronic data sharing; (3) conducting stakeholder public meetings to receive feedback on the use of electronic data sharing to communicate hazardous material shipping information; (4) collaborating with the Transportation Research Board on a study on the use of electronic hazardous materials shipping papers; (5) hosting workshops for stakeholders to communicate outreach findings of paperless hazardous communications; and (6) publishing e-HM information papers, which highlight the collective hazardous material transportation community's priorities, gaps, and concerns for implementing paperless hazard communications.

PHMSA strongly believes, through its prior efforts and activities, paperless hazard communication is possible and that this pilot program will demonstrate the capabilities of e-systems. PHMSA has developed a strategy for conducting the pilot projects that will enable PHMSA to evaluate paperless hazard communication systems capabilities from a real-world perspective.

The goal of the paperless hazard communications pilot program is to determine if e-systems are a feasible and effective means of providing hazard communication. In addition, if they are feasible and effective, PHMSA will use the information it gathers to assess the level of safety and security, as well as the associated benefits and costs, of e-systems as compared to the current hazardous materials shipping paper requirements. It is PHMSA's intent that any pilot project (test) conducted under the authority granted by MAP–21 will study the performance, safety and security impacts, and the associated benefits and costs of using e-systems for hazardous materials shipments, without disrupting the normal flow of commerce. During the pilot projects, emergency response providers and law enforcement officials will continue to perform their duties and respective roles according to existing emergency and inspection requirements, procedures, and policies. The emergency responders and law enforcement officials may continue to rely on the written shipping paper, even if companies are operating under a pilot project.

MAP–21 indicates that PHMSA must consider both the feasibility and the effectiveness of paperless hazard communications. Under this pilot program, PHMSA will be collaborating with regulated entities, law enforcement personnel, emergency response providers, and modal administrations to evaluate the feasibility and effectiveness of allowing e-HM communication for hazardous materials shipments. The pilot projects will focus on the use of e-systems:

- While shipping hazardous materials from point of origin to final destination using different transportation conveyances (i.e., trucks, railcars, maritime vessels, and airplanes), and
- During inspections and emergency response simulations.

PHMSA is seeking shippers, carriers, law enforcement personnel, and emergency responders that may be interested in volunteering to participate in the pilot projects. In response to a web posted announcement entitled, ''Defining the HM ACCESS Pilot Test,'' 64 entities expressed interest in participating. Some of these entities may satisfy the pilot project and MAP–21 qualification criteria and possess the capability and capacity to aid in testing a variety of scenarios. PHMSA strongly encourages the 64 entities that previously expressed interest in participating in the pilot projects to respond to this notice and provide the information identified within this notice. To ensure that we have the broadest range of participation in the pilot projects, PHMSA encourages other interested entities who have not previously expressed an interest in participating to volunteer. PHMSA will evaluate all volunteers (the previous 64 and those who respond to this notice) according to the criteria and qualifications identified in the following section and will select participants that satisfy the pilot test qualification requirements, meet the criteria specified in MAP–21, and are best able to aid in testing a variety of scenarios. Shippers, carriers, law enforcement, and emergency responders interested in participating in the pilot projects should provide statements of interest to the addresses identified in this notice. The statement of interest should include information describing the organization, point(s) of contact (name, title, address, phone, and email), self-identification of stakeholder type (shipper, carrier, law enforcement, or emergency responder), location, and capabilities. It should be noted, however, that responding to this notice does not guarantee selection for participation in the pilot projects.

4. Criteria Used for Selecting Pilot Project Participants

PHMSA intends that any pilot conducted under the authority granted by MAP–21 will study the performance, safety and security impacts, and associated benefits and costs of using e-systems for hazardous materials shipments, without disrupting the normal flow of commerce. Further, hardcopy shipping documents will still be required to accompany each shipment during the pilot projects, in accordance with the HMR.

PHMSA will conduct pilot tests in three, and potentially four, regions of the U.S.: The Northeast, Southeast, Northwest, and Southwest, with at least one pilot test conducted in a rural area within one or more of the regions, as prescribed by MAP–21. PHMSA will focus the pilot tests in geographical regions possessing high concentrations of hazardous materials registrants and presenting historically high numbers of hazardous material incidents resulting in deaths and injuries.

Law Enforcement and Emergency Response Volunteers

Desired law enforcement and emergency responder pilot test participants are those that operate within the regions of the pilot tests and are willing to assist in the collection of information during the tests, as described later in this document.

Shipper and Carrier Volunteers

Desired shipper and carrier pilot test participants are those who offer hazardous materials for transportation

and/or transport hazardous materials by a variety of modes and interact with other intermodal carriers for hazardous materials transfers. It is not PHMSA's intention to test vendors of electronic communication technologies or products. To volunteer and be selected as a volunteer, interested shipper and carrier participants will need to ship and/or transport hazardous materials within areas of high concentrations of hazardous materials registrants and hazardous materials incidents. In addition to the regions and modal criteria, potential participants must, at a minimum, satisfy the following requirements:

- Possess e-system(s) capable of managing and communicating the hazardous materials shipping paper information at their own expense,
- Possess their own equipment and personnel and/or contractor resources necessary to transport hazardous materials shipments,
- Be willing to allow, and participate in, inspections and emergency response simulations during the pilot tests,
- Be willing to provide feedback on experiences regarding e-HM communication during the pilot tests, including providing actual e-HM communications data from the pilot tests,
- Be willing to provide information on the basic function and capabilities of their e-system(s),
- Be willing to provide information on administrative, business, training, equipment, and operational-related benefits and costs associated with implementing e-system(s),
- Transport hazardous materials within the targeted test regions of the U.S., and
- Be in good standing with all levels of government and demonstrate compliance with all applicable regulations governing the safe and secure transportation of hazardous materials.

As part of PHMSA's participant evaluation and selection process, each shipper and carrier submitting a statement of interest will need to answer a list of on-line participant questions to verify its qualifications and capabilities. These questions will help PHMSA select those shipper and carrier participants that are best positioned to aid in testing a variety of test scenarios and criteria as specified in MAP–21. PHMSA anticipates the burden on shipper and carrier volunteers will be low and will involve the use of on-line questions (no more than 35 questions) with answers to most questions designed to be ''yes,'' ''no,'' or multiple choice.

Shipper and Carrier Participant Questions

PHMSA will publish a 30-day Notice in response to comments received to this 60-day Notice; the 30-day Notice will provide the shipper and carrier questions for those shippers and carriers who express an interest in volunteering in the pilot tests. PHMSA will use these questions to collect the following types of information from each shipper and carrier volunteer:

- Organization's name and general information.
- Hazardous material transport role (shipper, carrier, or both).
- Geographic area of business.
- Understanding of and ability to satisfy pilot test requirements and data needs.
- Technology of e-system(s).
- Capability of e-system(s) (scalability, accessibility, etc.).
- Equipment and process for transmitting data.
- Format of electronic data exchange.
- Class(es) of HM being shipped.
- Type of shipments(s) (less than truck load, bulk, etc.).
- Shipment route information (origin, destination, etc.).
- Mode(s) of transport associated with shipment(s).

PHMSA does not anticipate that completing the participant questions will impose a significant burden on shipper and carrier respondents. PHMSA estimates no more than 80 regulated entities (including those that have already replied to the web announcement and the additional volunteers that may reply to this Notice) will be asked to answer a list of shipper and carrier participant questions. PHMSA estimates it will take each respondent approximately 30 minutes to answer the list of participant questions. The resulting estimated total burden is 40 hours (80 respondents × 0.5 hour per respondent = 40 hours) for the shipper and carrier participant question data collection.

5. Request for Information (Following Selection of Pilot Test Participants)

PHMSA is seeking to collect: (1) Information and data as part of the pilot tests to support evaluation; and (2) data and information outside of the pilot tests for analyzing potential impacts (safety, security, benefits, and costs) of using e-systems.

PHMSA understands that this information collection effort may impose a burden on respondents. The information obtained will:

- Assist the agency in improving safety, hazard communication products, and/or hazard communication materials, and in potentially reducing current burden hours for completing shipping papers;
- Be provided strictly on a voluntary basis; and
- Be collected primarily utilizing on-line questions with answers to most questions designed to be ''yes,'' ''no,'' or multiple choice.

Volunteer modal inspectors and emergency responders will be responsible for conducting inspection and emergency response simulations and the majority of the data collection during the pilot tests. This approach limits the information burden on regulated entities, while minimizing information bias. Modal inspectors (typically law enforcement) will test the feasibility and effectiveness of e-systems by performing simulated modal inspections of regulated entities (shippers and carriers) participating in the pilot tests utilizing e-HM shipping papers. The inspectors will conduct each simulation following their established inspection protocols using their own existing equipment and resources. The only difference during the simulations will be that the shipping paper information will be communicated electronically. Following each inspection simulation, the participating inspector will answer a list of on-line questions related to the simulation and submit to PHMSA a copy of the e-HM shipping paper received. Emergency responders will follow a similar process to test the feasibility and effectiveness of e-systems during a simulated incident response involving HM shipments using electronic shipping papers. PHMSA will use the answers to the on-line questions and the e-HM shipping papers provided by the inspectors and emergency responders to evaluate the feasibility and effectiveness of the e-system involved.

PHMSA plans to administer the questions on-line q, with a maximum of 50 questions, and with answers to most questions designed to be ''yes,'' ''no,'' or multiple choice. The following sections summarize the types of information that will be requested as part of the pilot program.

Shipper and Carrier Information

Shippers and carriers will not be required to answer the list of on-line inspection and emergency response simulation questions described in the next section as part the pilot project. However, PHMSA does anticipate that the information provided by inspectors and emergency responders in conducting the simulations may

necessitate follow-up discussions with the shippers and/or carriers involved. Limited information may need to be collected from shippers and carriers as a result of these follow-up discussions, potentially including copies of e-HM shipping papers.

PHMSA does not anticipate that follow-up discussions with shippers and carriers and the associated information collection will impose a significant burden on respondents. PHMSA anticipates a total of 30 shippers and carriers (assuming 10 respondents for each of three test regions) and a burden of no more than four hours per shipper and carrier for the entirety of the test period. The resulting estimated total burden is 120 hours (30 respondents × 4.0 hour per respondent = 120 hours) for follow-up discussions and associated information collection with shippers and carriers.

Inspection Simulation Questions

For each hazardous materials inspection simulation, inspectors (law enforcement and/or Federal and state modal inspectors) involved in the simulation will answer a list of online inspection simulation questions and provide an electronic copy of the hazardous materials shipping paper they received during the simulation. Analysis of the e-HM shipping papers for required hazard communication information will enable PHMSA to verify the integrity of the data transfer. PHMSA will provide the list of inspection simulation questions with the 30-day Notice PHMSA will publish in response to comments received to this 60-day Notice. The inspection simulation questions will be designed to collect the following types of information:

- Organization's name and general information.
- Mode of transport inspected during simulation.
- Information about the organization's e-system(s).
- Activity triggering data transfer.
- Process and equipment used for data receipt and transmission.
- Hazardous materials data received from carrier or shipper.
- Hazardous materials data transmitted (to home office, other entity, etc.).
- Electronic data exchange format used.
- Actual time for data receipt (and transmission, if applicable).
- Human involvement.
- ''Readability'' of data.
- Electronic connectivity.
- Impacts to stakeholders (regulated entities, law enforcement, emergency responders, and the public).
- Impediments to using e-systems.
- Actual and potential benefits realized by stakeholders (regulated entities, law enforcement, emergency responders, and the public).

PHMSA does not anticipate that answering the list of inspection simulation questions will impose a significant burden on inspectors. PHMSA anticipates no more than 240 inspection simulations will be conducted (encompassing all pilot tests, all participants, and each test region throughout the entirety of the test period), resulting in a total of 240 respondents. PHMSA estimates it will take each inspector approximately 60 minutes to answer the list of inspection simulation questions and to submit a copy of the e-HM shipping paper to PHMSA. The resulting estimated total burden is 240 hours (240 respondents × 1.0 hour per respondent = 240 hours) for the inspection simulation question data collection.

Emergency Response Simulation Questions

For each hazardous materials emergency response simulation, emergency response providers and/or investigators involved in the simulation will answer a list of online emergency response simulation questions and provide an electronic copy of the hazardous materials shipping paper as received during the simulation. Analysis of the e-HM shipping papers for required hazard communication information will enable PHMSA to verify the integrity of the data transfer. PHMSA will provide the list of emergency response simulation questions with the 30-day Notice PHMSA will publish in response to comments received to this 60-day Notice. The emergency response simulation questions will be designed to collect the following types of information:

- Organization's name and general information.
- Mode of transport involved in the emergency response simulation.
- Information about the emergency response organization's e-system(s).
- Activity triggering data transfer.
- Process and equipment used for data receipt and transmission.
- Hazardous materials data received from carrier or shipper.
- Hazardous materials data transmitted (to first responders, etc.).
- Electronic data exchange format used.
- Actual time for data receipt (and transmission, if applicable).
- Human involvement.
- ''Readability'' of data.
- Electronic connectivity.
- Impacts to stakeholders (regulated entities, law enforcement, emergency responders, and the public).
- Impediments to using e-systems.
- Actual and potential benefits realized by stakeholders (regulated entities, law enforcement, emergency responders, and the public).

PHMSA does not anticipate that answering the list of emergency response simulation questions will impose a significant burden on investigators and emergency responders. PHMSA anticipates no more than 12 emergency response simulations will be conducted, resulting in a total of no more than 24 respondents (12 emergency response providers and 12 investigators). PHMSA estimates it will take each respondent approximately 60 minutes to answer the list of emergency response simulation questions and to submit a copy of the electronic shipping paper to PHMSA. The resulting estimated total burden is 24 hours (24 respondents × 1.0 hour per respondent = 24 hours) for the emergency response simulation question data collection.

Impact Analysis Questions

PHMSA is seeking to collect information and data from shippers, carriers, law enforcement, and emergency responders to aid in the assessment of potential impacts associated with using e-systems for each mode of transportation, as required under MAP–21. Potential impacts to be assessed include benefits, costs, safety, and security impacts on the public, emergency responders, and law enforcement. Similar to the pilot test simulation questions, PHMSA is planning to develop a list of impact analysis questions to be administered on-line, with a maximum of 75 questions, with answers to most questions designed to be ''yes,'' ''no,'' or multiple choice. PHMSA anticipates the list of impact analysis questions will not be limited to pilot test participants but will be available to all hazardous materials stakeholders to voluntarily answer. PHMSA will post the list of online impact analysis questions to the HM–ACCESS public Web site and distribute to industry via the HM–ACCESS email serve list. PHMSA will provide the list of impact analysis questions with the 30-day Notice PHMSA will publish in response to comments received to this 60-day Notice. The following list summarizes the types of information PHMSA plans to request as part of the impact analysis questions:

- Costs for required technology, including up-front capital costs for

equipment and ongoing costs for operations and maintenance (including telecommunications, any third-party service providers, maintenance of equipment, etc.).

- Costs for training personnel.
- Costs for conducting outreach/education to customers on the new approach.
- Changes in administrative costs and time requirements for:
- Generating e-HM shipping papers (vs. current hardcopy approach), including data entry.
- Filing, storing, and retrieving hardcopy shipping papers.
- Coordinating between shipper and carrier and between different carriers/modes in the supply chain (e.g., any changes in the paperwork that is created when a shipment goes from rail to truck).
- Impacts on operations (e.g. transport times, vehicle utilization, employee productivity, etc.).
- Any associated changes to other business processes (e.g., switching from paper to electronic invoices) and their costs/impacts.
- Changes in error rates for shipping papers.
- Information on the administrative, business, training, equipment, and operational-related costs and benefits associated with implementing e-system(s).
- Insurance and risk management issues/cost impacts.
- Any associated information that must be included to communicate hazard information.
- Limitation of e-system capability to communicate information and identifying the redundancy if failure exists.
- Information concerning the release of commercially-sensitive information.
- Unintentional release of information from unauthorized access.

PHMSA does not anticipate that answering the list of impact analysis questions will impose a significant burden on respondents (shippers, carriers, law enforcement, and emergency responders). PHMSA estimates no more than 200 respondents will complete the impact analysis questions, and that it will take each respondent approximately 90 minutes to answer the questions. The resulting estimated total burden is 300 hours (200 respondents × 1.5 hours per respondent = 300 hours) for the impact analysis question data collection.

The information previously described is intended to ensure that evaluation and feasibility reports focus on results and include quantitative data on the recommendation and possible implementation of e-systems into the Federal hazardous materials transportation safety program. This information and data will enable PHMSA to more accurately assess the safety and security impacts of using e-systems and to analyze the associated benefits and cost of using the e-systems.

6. Total Information Collection Burden

The total information collection burden for the Paperless Hazard Communication Pilot Program is as follows:

Participant Questions:	80 respondents × 0.5 hr.	=	40 hours
Shipper and Carrier Information:	30 respondents × 4.0 hr.	=	120 hours
Inspection Questions:	240 respondents × 1.0 hr.	=	240 hours
Emergency Response Questions:	24 respondents × 1.0 hr.	=	24 hours
Impact Analysis Questions:	200 respondents × 1.5 hr.	=	300 hours
Total Information Collection Burden:	**574 respondents**	....	**724 hours**

Title: Paperless Hazard Communications Pilot Program.

Type of Request: Request for Comments to Information Collection Burden for Paperless Hazard Communications Pilot Program.

Abstract: PHMSA is submitting an information collection to OMB in support of a paperless hazard communications pilot program under Title III, Section 33005 of the Hazardous Materials Transportation Safety Improvement Act of 2012 (MAP–21).

Affected Public: Carriers, Shippers, Emergency Response Providers, and Law Enforcement Personnel

Estimated Number of Respondents: 574.

Estimated Number of Responses: 574.

Estimated Annual Burden Hours: 724.

Estimated Annual Burden Costs: $24,300.

Frequency of collection: Single occasion.

Issued in Washington, DC, on July 16, 2013.

Magdy El-Sibaie,

Associate Administrator for Hazardous Materials Safety.

[FR Doc. 2013–17363 Filed 7–18–13; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Special Permit Applications

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on Special Permit Applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR Part 107, Subpart B), notice is hereby given of the actions on special permits applications in (June to June 2013). The mode of transportation involved are identified by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft. Application numbers prefixed by the letters EE represent applications for Emergency Special Permits. It should be noted that some of the sections cited were those in effect at the time certain special permits were issued.

Issued in Washington, DC, on July 15, 2013.

Donald Burger,

Chief, General Approvals and Permits.

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
MODIFICATION SPECIAL PERMIT GRANTED			
4576–M	Structural Composites Industries (SCI) Pomona, CA.	49 CFR 173.302a and 173.304a.	To modify the special permit to authorize additional Division 2.1 and 2.2 materials and add Division 2.3 materials.

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
10915–M	Luxfer Gas Cylinders Riverside, CA.	49 CFR 173.302a, 173.304a and 180.205.	To modify the special permit to authorize a new maximum allowable working pressure and maximum allowable strength stiffness.
13581–M	Bengal Products Inc. Baton Rouge, LA.	49 CFR 173.306(a)(3)	To modify the special permit to reflect current statutes and regulations pertaining to consumer commodities.
15389–M	AMETEK Ameron LLC d/b/a MASS Systems Baldwin Park, CA.	49 CFR 173.301(a)(1), 173.301(a)(1), 173.302a(a)(1), and 173.304a(a)(1).	To modify the special permit to authorize new pressure test requirements.
13112–M	Carleton Technologies Inc. (Former Grantee: Conax Florida Corporation dba Cobham Life Support) Orchard Park, NY.	49 CFR 173.302a	To modify the special permit to change a drawing number; replace the fully assembled pressure vessel with a representative pyrotechnic primer; increase the required temperature per minute for gas relief; require a nominal operating pressure; reduce the testing frequency; and remove the flattening test.
14856–M	BKC Industries, Inc. Creedmoor, NC.	49 CFR 180.209(a) and (b)	To modify the special permit to authorize neck thread requirements that are consistant with CGA Pamphlet C–23.
14828–M	Croman Corporation White City, OR.	49 CFR 172.101 Column (9B), 172.204(c)(3), 173.27(b)(2) and (3), 175.30 and 175.75.	To modify the special permit to authorize the addition of Division 1.2 explosives.
8228–M	U.S. Department of Justice, Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) Washington, DC.	49 CFR 172.101(c), 172.203(k), 172.102, and 173.56(b).	To modify the special permit to authorize an alternative packaging.
15028–M	Roeder Cartage Company, Inc. Lima, OH.	49 CFR 180.407(c), (e), and (f).	To modify the special permit to authorize a DOT specification 407 trailer.
		NEW SPECIAL PERMIT GRANTED	
15792–N	American Spraytech North Branch, NJ.	49 CFR 173.306(a)(3)(v)	To authorize the transportation in commerce of certain aerosols containing a Division 2.2 compressed gas in non-refillable aerosol containers which are not subject to the hot water bath test. (mode 1)
15799–N	Consumer Products Safety Commission (CPSC) Bethesda, MD.	49 CFR 173.21(i)	To authorize the one way transportation in commerce of lighters without LA approvals. (modes 1, 4)
15778–N	Northwest Helicopters, LLC Olympia, WA.	49 CFR § 172.101 Column (9B), § 172.204(c)(3), § 173.27(b)(2), § 175.30(a)(1), §§ 172.200, 172.300, 172.400, 173.302(f)(3) and § 175.75.	To authorize the transportation in commerce of certain hazardous materials by Part 133 Rotorcraft External Load Operations, attached to or suspended from an aircraft, in remote areas of the US without meeting certain hazard communication and stowage requirements. (mode 4)
15851–N	Conair Corporation East Windsor, NJ.	49 CFR 171.2(k)	To authorize the transportation in commerce of certain used DOT 3AL cylinders that contain CO2, but not necessarily in an amount qualifying as hazardous material. (modes 1, 2, 3, 4, 5)
15836–N	Galyean LP Henderson, TX	49 CFR 173.202, 173.203, 173.241, 173.242 and 173.243.	To authorize the transportation in commerce of certain Class 3 and Class 8 materials in alternative packaging for transportation by motor vehicle. (mode 1)
15838–N	Primo Water Corporation Winston-Salem, NC.	49 CFR 171.2(k)	To authorize the transportation in commerce of certain used cylinders that contain CO2, but not necessarily in an amount qualifying as hazardous material. (modes 1, 2, 3, 4)
15860–N	Apple Inc. Cupertino, CA	49 CFR 173.185(a)	To authorize the transportation in commerce of damaged or defective lithium ion batteries that do not meet the requirements of § 173.185(a) (modes 1, 3)
15827–N	Advanced Chemical Transport Sunnyvale, CA.	49 CFR 173.185(a)	To authorize the manufacture, marking, sale an use of certain packagings for spent lithium ion batteries that have not been tested in accordance with the UN Manual of Test Criteria. (modes 1, 3)
15877–N	ConocoPhillips Alaska, Inc. Anchorage, AK.	49 CFR 172.101(9B)	To authorize the transportation in commerce of certain flammable or corresive liquids which exceed that quantity limitations when transported by cargo aircraft. (mode 4)
15878–N	ConAgra Foods Naperville, IL	49 CFR 172.304(a)(3)	To authorize the transportation in commerce of certain packages whose limited quantity marking is partially overprinted by a display instruction. (mode 1)
15871–N	Shell Chemical LP Deer Park, TX.	49 CFR 171.2(g)	To authorize the transportation in commerce of certain 111A100W3 railcars containing Phenol with steam jacketed vent valves that were converted at a non-registered fabrication shop. (mode 2)
15879–N	Kalitta Air, LLC Ypsilanti, MI ...	49 CFR 172.101 Column (9B), 172.204(c)(3), 173.27, and 175.30(a)(1).	To authorize the one-time transportation in commerce of certain explosives that are forbidden for transportation by cargo only aircraft. (mode 4)

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
15846–N	LDJ Manufacturing, Inc. Pella, IA.	49 CFR 178.346–4(b)	To authorize the manufacture, marking, sale and use of non-DOT specification cargo tanks similar to DOT 406 except that external self-closing stop-valves are authorized. (mode 1)
DENIED			
14520–M	Request by Axiall Corporation Monroeville, PA June 06, 2013.		
15745–N	Request by Praxair Distribution, Inc. Danbury, CT June 10, 2013. To authorize the transportation in commerce of certain foreign manufactured cylinders qualified under an alternative test method and which are not equipped with pressure relief devices.		

[FR Doc. 2013–17278 Filed 7–18–13; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Office of Hazardous Materials Safety; Notice of Application for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of Applications for Special Permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR Part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before August 19, 2013.

Address Comments To: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington DC or at *http://regulations.gov.*

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on July 15, 2013.

Donald Burger,

Chief, General Approvals and Permits.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of special permits thereof
NEW SPECIAL PERMITS				
15865–N	.....	HeliStream Inc. Costa Mesa, CA.	49 CFR 49 CFR Table § 172.101, Column(9B), § 172.204(c)(3), § 173.27(b)(2) § 175.30(a)(1) § 172.200, 172.300, and 172.400.	To authorize the transportation in commerce of certain hazardous materials by 14 CFR Part 133 Rotorcraft External Load Operations transporting hazardous materials attached to or suspended from an aircraft, in remote areas of the US only, without being subject to hazard communication requirements, quantity limitations and certain loading and stowage requirements. (mode 4)
15880–N	.....	Viking Packing Specialist Catoosa, OK.	49 CFR 173.60	Authorizes the transportation in commerce of not more than 5 grams of Division 1.4C materials in a special shipping container. (modes 1, 4, 5)
15881–N	.....	Chart Industries, Inc. Ball Ground, GA.	49 CFR 180.211(c)(2)(i)	To authorize the repair of certain DOT 4L cylinders without requiring pressure testing. (mode 1)
15882–N	.....	Ryan Air Anchorage, AK ..	49 CFR 172.101 Table Column (9B), 173.27 and 173.243.	To authorize the transportation in commerce of certain Class 3 fuels in non-DOT specification bulk packaging by cargo aircraft. (mode 4)

[FR Doc. 2013–17280 Filed 7–18–13; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

List of Applications Delayed

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications delayed more than 180 days.

SUMMARY: In accordance with the requirements of 49 U.S.C. 5117(c), PHMSA is publishing the following list of special permit applications that have been in process for 180 days or more. The reason(s) for delay and the expected completion date for action on each application is provided in association with each identified application.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Special Permits

and Approvals, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

Key to ''Reason for Delay''

1. Awaiting additional information from applicant
2. Extensive public comment under review
3. Application is technically complex and is of significant impact or precedent-setting and requires extensive analysis
4. Staff review delayed by other priority issues or volume of special permit applications

Meaning of Application Number Suffixes

N—New application
M—Modification request
R—Renewal Request
P—Party To Exemption Request

Issued in Washington, DC, on July 15, 2013.

Donald Burger,

Chief, General Approvals and Permits.

Application No.	Applicant	Reason for delay	Estimated date of completion
New Special Permit Applications			
15720–N	Digital Wave Corporation Centennial, CO	3,1	07–31–2013
15747–N	UPS, Inc. Atlanta, GA	2,3	07–31–2013
15755–N	Micronesian Aviation Corporation dba Americopters Saipan, MP	4	07–31–2013
15727–N	Blackhawk Helicopters El Cajon, CA	4	07–31–2013
15767–N	Union Pacific Railroad Company Omaha, NE	1	07–31–2013
15788–N	Amtrol-Alfa, Metalomecanica SA Portugal	4	07–31–2013
Renewal Special Permits Applications			
15251–R	Suburban Air Freight, Inc. Omaha, NE	3	07–31–2013
14996–R	Skydance Helicopters of Northern Nevada Minden, NV	1,4	07–31–2013
11136–R	Fireworks by Grucci Brookhaven, NY	4	07–31–2013

[FR Doc. 2013–17277 Filed 7–18–13; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Office of Hazardous Materials Safety; Notice of Applications for Modification of Special Permit

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR Part 107, Subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier **Federal Register** publications, they are not repeated here. Requests for modification of special permits (e.g. to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix ''M'' denote a modification request. These applications have been separated from the new application for special permits to facilitate processing.

DATES: Comments must be received on or before August 5, 2013.

Address Comments To: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington DC or at *http://regulations.gov.*

This notice of receipt of applications for modification of special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington DC, on July 15, 2013.

Donald Burger,

Chief, General Approvals and Permits.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of special permit thereof
MODIFICATION SPECIAL PERMITS				
11352–M		PepsiCo, Inc. Arlington, TX.	49 CFR 172.200; 172.300; 172.400; 172.500	To modify the special permit to authorize additional Class 3, 8, and 9 materials.
11947–M		Patts Fabrication, Inc. Midland, TX.	49 CFR 173.202; 173.203; 173.241; 173.242	To modify the special permit to authorize additional Class 3 and 8 materials.
13133–M		Department of Defense Scott AFB, IL.	49 CFR 172.320; 173.54(a); 173.56(b); 173.57; 173.58; 173.62	To modify the special permit to remove the requirement that new explosive substances must be tested and pass the UN Test Series 3 tests.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of special permit thereof
15110–M	.....	Kidde Technologies, Inc., dba Kidde Aerospace & Defense Wilson, NC.	49 CFR 178.65	To modify the special permit to authorize minor dimensional changes for the existing developmental drawing 348711 which is part of weldment design 447235, the addition of two new weldment designs, two additional Division 2.2 materials, and the use of these cylinders as components on US Naval Aircraft.
15634–M	.....	SodaStream USA Mount Laurel, NJ.	49 CFR 171.2(k)	To modify the special permit to authorize the transportation of cylinders by motor vehicle consistent with the limited quanitiy exception.
15691–M	.....	Department of Defense Scotts AFB, IL.	49 CFR 180.209	To reissue the special permit originally issued on an emergency basis.

[FR Doc. 2013–17279 Filed 7–18–13; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF TRANSPORTATION

Research & Innovative Technology Administration

[Docket ID Number RITA 2008–0002]

Agency Information Collection; Activity Under OMB Review; Report of Passengers Denied Confirmed Space—BTS Form 251

AGENCY: Research & Innovative Technology Administration (RITA), Bureau of Transportation Statistics (BTS), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Transportation Statistics invites the general public, industry and other governmental parties to comment on the continuing need for and usefulness of BTS collecting reports on the number of passengers holding confirmed reservations that voluntarily or involuntarily give up their seats when the airline oversells the flight. Comments are requested concerning whether (a) the collection is still needed by the Department of Transportation, (b) BTS accurately estimated the reporting burden; (c) there are other ways to enhance the quality, utility and clarity of the information collected; and (d) there are ways to minimize reporting burden, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted by September 17, 2013.

FOR FURTHER INFORMATION CONTACT: Cecelia Robinson, Office of Airline Information, RTS–42, Room E34–410, RITA, BTS, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, Telephone Number (202) 366–4405, Fax Number (202) 366–3383 or EMAIL *cecelia.robinson@dot.gov*.

COMMENTS: Comments should identify the associated OMB approval #2138–0018 and Docket ID Number RITA 2008–0002. Persons wishing the Department to acknowledge receipt of their comments must submit with those comments a self-addressed stamped postcard on which the following statement is made: Comments on OMB # 2138–0018, Docket—RITA 2008–0002. The postcard will be date/time stamped and returned.

SUPPLEMENTARY INFORMATION:

OMB Approval No.: 2138–0018.

Title: Report of Passengers Denied Confirmed Space.

Form No.: BTS Form 251.

Type of Review: Reinstatement of an expired approved collection.

Respondents: Large certificated air carriers.

Number of Respondents: 16.

Number of Responses: 64.

Total Annual Burden: 640 hours.

Needs and Uses: BTS Form 251 is a one-page report submitted four times per year, on the number of passengers denied seats either voluntarily or involuntarily, whether these bumped passengers were provided alternate transportation and/or compensation, and the amount of the payment. U.S. air carriers that account for at least 1 percent of domestic scheduled-service passenger revenues must report oversales on all operations with 30 seats or larger aircraft that depart a U.S. airport.

Carriers do not report data from inbound international flights to the United States because the protections of 14 CFR part 250 *Oversales* do not apply to these flights. The report allows the Department to monitor the effectiveness of its oversales rule and take enforcement action when necessary. The involuntarily denied-boarding rate has decreased from 4.38 per 10,000 passengers in 1980 to 0.71 for the quarter ended December 2011. Without Form 251, determining the effectiveness of the Department's oversales rule would be impossible. The publishing of the carriers' individual denied boarding rates has diminished the need for more intrusive regulation. The rate of denied boarding can be examined as a continuing fitness factor. This rate provides an insight into a carrier's customer service practices. A rapid sustained increase in the rate of denied boarding may indicate operational difficulties. Because the rate of denied boarding is released quarterly, travelers and travel agents can select carriers with lower incidences of bumping passengers. This information is available in the *Air Travel Consumer Report* at: *http://airconsumer.ost.dot.gov/reports/index.htm*. The *Air Travel Consumer Report* is also sent to newspapers, magazines, and trade journals. The public availability of this information deters carriers from setting unreasonable overbooking rates—a market-based mechanism that is more efficient than direct regulation of those rates.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501 note) requires a statistical agency to clearly identify information it collects for non-statistical purposes. BTS hereby notifies the respondents and the public that BTS uses the information it collects under this OMB approval for non-statistical purposes including, but not limited to, publication of both Respondent's identity and its data, submission of the information to agencies outside BTS for review, analysis, and possible use in regulatory and other administrative matters.

Issued in Washington, DC, on July 12, 2013.

Patricia Hu,

Director, Bureau of Transportation Statistics, Research and Innovative Technology Administration.

[FR Doc. 2013–17281 Filed 7–18–13; 8:45 am]

BILLING CODE 4910–HY–P

DEPARTMENT OF TRANSPORTATION

Research and Innovative Technology Administration

Intelligent Transportation Systems Program Advisory Committee; Notice of Meeting

AGENCY: ITS Joint Program Office, Research and Innovative Technology Administration, U.S. Department of Transportation.

ACTION: Notice.

The Intelligent Transportation Systems (ITS) Program Advisory Committee (ITS PAC) will hold a meeting on August 7, 2013, from 8:00 a.m. to 4:00 p.m. (EST), and on August 8, 2013, from 8:00 a.m. to 4:00 p.m. (EST) in Salon F of the Crystal City Marriott at Reagan National Airport, 1999 Jefferson Davis Highway, Arlington, VA 22202.

The ITS PAC, established under Section 5305 of Public Law 109–59, Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, August 10, 2005, and re-established under Section 53003 of Public Law 112–141, Moving Ahead for Progress in the 21st Century, July 6, 2012, was created to advise the Secretary of Transportation on all matters relating to the study, development, and implementation of intelligent transportation systems. Through its sponsor, the ITS Joint Program Office (JPO), the ITS PAC makes recommendations to the Secretary regarding ITS Program needs, objectives, plans, approaches, content, and progress.

The following is a summary of the tentative meeting agenda. August 7: (1) ITS JPO Program Update, (2) Review of Draft NHTSA Letter, (3) Discussion of Report on Deployment Incentives, (4) ITS Strategic Plan Update, and (5) Committee Discussion of ITS Strategic Plan Review. August 8: (1) Subcommittee Meetings to Finalize Recommendations to the Secretary of Transportation (Secretary), (2) Subcommittee Reports on Recommendations to the Secretary, and (3) Discussion of Final Recommendations to the Secretary.

The meeting will be open to the public, but limited space will be available on a first-come, first-served basis. Members of the public who wish to present oral statements at the meeting must request approval from Mr. Stephen Glasscock, the Committee Designated Federal Official, at (202) 366–9126, no later than July 31, 2013.

Questions about the agenda or written comments may be submitted by U.S. Mail to: U.S. Department of Transportation, Research and Innovative Technology Administration, ITS Joint Program Office, Attention: Stephen Glasscock, 1200 New Jersey Avenue SE., HOIT, Washington, DC 20590 or faxed to (202) 493–2027. The ITS Joint Program Office requests that written comments be submitted not later than July 31, 2013.

Notice of this meeting is provided in accordance with the Federal Advisory Committee Act and the General Services Administration regulations (41 CFR Part 102–3) covering management of Federal advisory committees.

Issued in Washington, DC, on the 15th day of July 2013.

John Augustine,

Managing Director, ITS Joint Program Office.

[FR Doc. 2013–17358 Filed 7–18–13; 8:45 am]

BILLING CODE 4910–HY–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 290 (Sub-No. 343X)]

Central of Georgia Railroad Company—Abandonment Exemption—in Newton County, Ga.

Central of Georgia Railroad Company (CGA) [1] has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon approximately 14.90 miles of rail line between milepost E 65.80 (at the point of the line's crossing of Route 229 in Newborn) and milepost E 80.70 (near the intersection of Washington Street SW., and Turner Lake Road SW., in Covington), in Newton County, Ga. The line traverses United States Postal Service Zip Codes 30014, 30055, and 30056.

CGA has certified that: (1) No local traffic has moved over the line for at least two years; (2) no overhead traffic has moved over the line for at least two years, and if there were any overhead traffic, it could be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on August 20, 2013, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[3] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by July 29, 2013. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by August 8, 2013, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to CGA's representative: Robert A. Wimbish, Baker & Miller PLLC, 2401 Pennsylvania Ave. NW., Suite 300, Washington, DC 20037.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

CGA has filed a combined environmental and historic report that addresses the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by July 26, 2013. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service at (800) 877–8339. Comments on environmental and historic preservation matters must be

[1] CGA is a wholly owned subsidiary of Norfolk Southern Railway Company.

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C. 2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[3] Each OFA must be accompanied by the filing fee, which is currently set at $1,600. *See* 49 CFR 1002.2(f)(25).

filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), CGA shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by CGA's filing of a notice of consummation by July 19, 2014, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at ''*www.stb.dot.gov.*''

Decided: July 12, 2013.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Derrick A. Gardner,

Clearance Clerk.

[FR Doc. 2013–17282 Filed 7–18–13; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35750]

Ramsey County Regional Railroad Authority—Acquisition Exemption—Right to Restore Rail Service Over a Railbanked Right-of-Way in Ramsey County, Minn.

Ramsey County Regional Railroad Authority (RCRRA), a noncarrier political subdivision of the State of Minnesota, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire from the City of Maplewood, Minn. (the City), the right to restore rail service over a rail banked right-of-way, a distance of .67 miles, extending between milepost 7.19, approximately 100 feet north of Interstate Highway I–694 in White Bear Township, and milepost 6.52, approximately 50 feet north of Beam Avenue in the City (the line), in Ramsey County, Minn.

In a related prior transaction, BNSF Railway Company (BNSF) filed a verified notice of exemption to abandon the line,[1] and the Board issued a Notice of Interim Trail Use or Abandonment (NITU) under section 8(d) of the National Trails System Act, 16 U.S.C. 1247(d), and 49 CFR 1152.29 to permit the City to negotiate with BNSF to acquire the line for use as a trail (rail banking/interim trail use).[2] On October 28, 2005, the parties filed, in the abandonment docket, a notice that a rail banking/interim trail use agreement had been reached.[3] By quitclaim deed dated September 26, 2005, BNSF conveyed the line to the City along with BNSF's right to restore service over the right-of-way. The City obtained Board authority to acquire the right to restore rail service in 2010.[4] The City stated that it or an operator contracted by the City would operate over the line if service were restored.

The City and RCRRA now seek to convey the right to restore rail service over the right-of-way from the City to RCRRA.[5] The parties state that an agreement between RCRRA and the City has been reached for RCRRA's acquisition of the City's right to restore rail service over the right-of-way. RCRRA or an operator contracted by RCRRA would operate the rail line if rail service were to be restored.

The transaction is expected to be consummated on or after August 2, 2013 (30 days after the exemption was filed).

RCRRA certifies that its projected annual revenues from the acquisition involved in this proceeding do not exceed $5 million or exceed those that would qualify it as a Class III carrier.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than July 26, 2013 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35750, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Thomas F. McFarland, Thomas F. McFarland, P.C., 208 South LaSalle Street, Suite 1890, Chicago, IL 60604–1112.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: July 12, 2013.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Derrick A. Gardner,

Clearance Clerk.

[FR Doc. 2013–17275 Filed 7–18–13; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

July 16, 2013.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before August 19, 2013 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.GOV* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov,* or the entire information collection request maybe found at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Number: 1545–0007.

Type of Review: Extension without change of a currently approved collection.

Title: Forest Activities Schedule.

Form: T.

Abstract: Form T is filed by individuals and corporations to report income and deductions from the operation of a timber business. The IRS uses Form T to determine if the correct amount of income and deductions are reported.

Affected Public: Private Sector; Businesses or other for-profits.

[1] *BNSF Railway—Aban. Exemption—in Ramsey Cnty., Minn.,* AB 6 (Sub.-No. 429X) (STB served Aug. 10, 2005).

[2] *BNSF Railway—Aban. Exemption—in Ramsey Cnty., Minn.,* AB 6 (Sub.-No. 429X) (STB served Sept. 8, 2005).

[3] *See* Notice of Interim Trail Use Agreement, *BNSF Railway—Aban. Exemption—in Ramsey Cnty., Minn.,* AB 6 (Sub.-No. 429X) (filed Oct. 28, 2005).

[4] *City of Maplewood, Minn.—Aquis. Exemption—Right to Restore Rail Serv. Over a Railbanked Right-of-Way in Ramsey Cnty., Minn.,* FD 35450 (STB served Dec. 23, 2010).

[5] RCRRA and the City have also filed a petition to substitute trail user, pursuant to which RCRRA seeks to become the trail sponsor of the line. *BNSF Railway—Aban. Exemption—in Ramsey Cnty., Minn.,* AB 6 (Sub.-No. 429X) (filed July 3, 2013).

Estimated Annual Burden Hours: 446,208.

OMB Number: 1545–0159.

Type of Review: Revision of a currently approved collection.

Title: Annual Return To Report Transactions With Foreign Trusts and Receipts of Certain Foreign Gifts.

Form: 3520.

Abstract: Form 3520 is filed by U.S. persons who create a foreign trust, transfer property to a foreign trust, receive a distribution from a foreign trust, or receive a large gift from a foreign source. IRS uses the form to identify the U.S. persons who may have transactions that may trigger a taxable event in the future.

Affected Public: Private Sector: Businesses and other for-profits.

Estimated Annual Burden Hours: 71,742.

OMB Number: 1545–0213.

Type of Review: Extension without change of a currently approved collection.

Title: Annual Certification of Racial Nondiscrimination for a Private School Exempt from Federal Income Tax.

Form: 5578.

Abstract: Form 5578 is used by private schools that do not file Schedule A (Form 990) to certify that they have a racially nondiscriminatory policy toward students as outlined in Revenue Procedure 75–50. The Internal Revenue Service uses the information to help ensure that the school is maintaining a nondiscriminatory policy in keeping with its exempt status.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Annual Burden Hours: 3,730.

OMB Number: 1545–0742.

Type of Review: Extension without change of a currently approved collection.

Title: TD 8019—Public Inspection of Exempt Organization Return.

Abstract: Section 6104(b) authorizes the Service to make available to the public the returns required to be filed by exempt organizations. The information requested in § 301.6104(b)–1(b)(4) is necessary in order for the Service not to disclose confidential business information furnished by businesses which contribute to exempt black lung trusts.

Affected Public: Private Sector: Businesses and other for-profits.

Estimated Annual Burden Hours: 22.

OMB Number: 1545–0768.

Type of Review: Extension without change of a currently approved collection.

Title: TD 7898—Employers Qualified Educational Assistance Programs.

Abstract: Respondents include employers who maintain education assistance programs for their employees. Information verifies that programs are qualified and that employees may exclude educational assistance from their gross incomes.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 615.

OMB Number: 1545–0949.

Type of Review: Extension without change of a currently approved collection.

Title: Application for Special Enrollment Examination.

Form: 2587.

Abstract: This information relates to the determination of the eligibility of individuals seeking enrollment status to practice before the Internal Revenue Service.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 11,000.

OMB Number: 1545–1093.

Type of Review: Extension without change of a currently approved collection.

Title: TD 8416—Final Minimum Tax-Tax Benefit Rule.

Abstract: Section 58(h) of the Internal Revenue Code provides that the Secretary shall provide for adjusting tax preference items where such items provided no tax benefit for any taxable year. This regulation provides guidance for situations where tax preference items provided no tax benefit because of available credits and describes how to claim a credit or refund of minimum tax paid on such preferences.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 40.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2013–17326 Filed 7–18–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Transfer Agent Registration and Amendment Form

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; and Federal Deposit Insurance Corporation (FDIC) .

ACTION: Notice and Request for Comment.

SUMMARY: The Office of the Comptroller of the Currency (OCC) and Federal Deposit Insurance Corporation (FDIC) are announcing that a proposed collection of information renewal is being submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Comments must be submitted on or before August 19, 2013.

ADDRESSES:

OCC: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0124, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *regs.comments@occ.treas.gov*. You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FDIC: You may submit comments, which should refer to ''Transfer Agent Registration and Amendment Form, 3064–0026'' by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *Email: comments@FDIC.gov*. Include ''Transfer Agent Registration and Amendment Form, 3064–0026'' in the subject line of the message.
- *Mail:* Gary A. Kuiper (202 898–3877, Attn: Comments, Federal Deposit Insurance Corporation, 550 17th Street NW., NYA–5046, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building

(located on F Street) on business days between 7 a.m. and 5 p.m.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0124 or 3064–0026, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: *oira_submission@omb.eop.gov*.

Public Inspection: All comments received will be posted without change to *http://www.fdic.gov/regulations/laws/federal/notices.html* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: For further information about the information collection discussed in this notice, please contact any of the agency clearance officers whose names appear below.

OCC: Johnny Vilela or Mary H. Gottlieb, OCC Clearance Officers, (202) 649–5490, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219.

FDIC: Gary A. Kuiper, (202) 898–3877, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW., NYA–5046, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, the OCC and FDIC are submitting the following proposed collection of information to OMB for review and clearance.

Report Title: Transfer Agent Registration and Amendment Form.

Form Number: TA–1.

Frequency of Response: On occasion.

Affected Public: Business or other for-profit.

Estimated Time per Response: 1.25 hours: registration, 10 minutes: amendment.

OCC

OMB Number: 1557–0124.

Estimated Number of Respondents: 2 registrations, 15 amendments.

Estimated Total Annual Burden: 6 hours.

FDIC

OMB Number: 3064–0026.

Estimated Number of Respondents: 2 registrations, 13 amendments.

Estimated Total Annual Burden: 5 hours.

Abstract

The Securities Exchange Act of 1934 (Act) requires any person acting as a transfer agent to register as such and to amend registration information when it changes. Section 17A(c) of the Act requires all transfer agents for securities registered under section 12 of the Act to register ''by filing with the appropriate regulatory agency . . . an application for registration in such form and containing such information and documents . . . as such appropriate regulatory agency may prescribe as necessary or appropriate in furtherance of the purposes of this section.'' In general, an entity performing transfer agent functions for a security is required to register if the security is registered on a national securities exchange and if the issuer has total assets of $10 million or more and a class of equity security held of record by 500 or more persons.

General Description of Reports

This information collection is mandatory pursuant to Sections 17A(c), 17(a)(3), and 23(a) of the Act, as amended (15 U.S.C. 78q–1(c), 78q(a)(3), and 78w(a)) (FDIC). Sections 12, 13, 14(a), 14(c), 14(d), 14(f), and 16 of the Act, as amended (15 U.S.C. 781, 78m, 78n(a), 78n(c), 78n(d), 78n(f), and 78p (OCC). Additionally, § 341.3 of the FDIC's Rules and Regulations implement the provisions of the Act. The registrations are public filings and, therefore, are not confidential.

On May 3, 2013, the OCC and FDIC published in the **Federal Register** (78 FR 26113), a 60-day notice requesting public comment on the proposed collection of information. They received no comments.

Request for Comment

The Agencies invite comment on:

(a) Whether the collections of information are necessary for the proper performance of the Agencies' functions, including whether the information has practical utility;

(b) The accuracy of the Agencies' estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be shared among the Agencies. All comments will become a matter of public record.

Dated: July 15, 2013.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division.

Dated at Washington, DC, this 11th day of July, 2013.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2013–17384 Filed 7–18–13; 8:45 am]

BILLING CODE 4810–33–P ; 6714–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Information Collection Renewal; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the renewal of an information collection, as required by the Paperwork Reduction Act of 1995 (PRA). An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning renewal of an information collection titled, ''Guidance on Sound Incentive Compensation Practices.''

DATES: Written comments should be submitted by September 17, 2013.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0245, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *regs.comments@occ.treas.gov*. You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not

enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: You can request additional information or a copy of the collection from Johnny Vilela or Mary H. Gottlieb, OCC Clearance Officers, (202) 649–5490, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is requesting renewal, without change of the following collection:

Title: Guidance on Sound Incentive Compensation Policies.

OMB Number: 1557–0245.

Abstract: Under the guidance, national banks and Federal savings associations are required to: (i) Have policies and procedures that identify and describe the role(s) of the personnel and units authorized to be involved in incentive compensation arrangements, identify the source of significant risk-related inputs, establish appropriate controls governing these inputs to help ensure their integrity, and identify the individual(s) and unit(s) whose approval is necessary for the establishment or modification of incentive compensation arrangements; (ii) create and maintain sufficient documentation to permit an audit of the organization's processes for incentive compensation arrangements; (iii) have any material exceptions or adjustments to the incentive compensation arrangements established for senior executives approved and documented by its board of directors; and (iv) have its board of directors receive and review, on an annual or more frequent basis, an assessment by management of the effectiveness of the design and operation of the organization's incentive compensation system in providing risk-taking incentives that are consistent with the organization's safety and soundness.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 1,033 large banks; 1,991 small banks.

Estimated Burden per Respondent: 520 hours for large banks; 52 hours for small banks.

Frequency of Response: Annually.

Total Annual Burden: 640,692 hours. All comments will be considered in formulating the subsequent submission and become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCCs estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: July 15, 2013.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division.

[FR Doc. 2013–17383 Filed 7–18–13; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Designation and Identification of Two (2) Individuals and Two (2) Entities Pursuant to Executive Orders 13572 of April 29, 2011, ''Blocking Property of Certain Persons With Respect to Human Rights Abuses in Syria'' and 13582 of August 17, 2011, ''Blocking Property of the Government of Syria and Prohibiting Certain Transactions With Respect to Syria''

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (''OFAC'') is publishing the names of two (2) individuals and two (2) entities whose property and interests in property are blocked pursuant to Executive Orders 13572 of April 29, 2011, ''Blocking Property of Certain Persons with Respect to Human Rights Abuses in Syria'' and 13582 of August 17, 2011 ''Blocking Property of the Government of Syria and Prohibiting Certain Transactions with Respect to Syria.''

DATES: The actions by the Director of OFAC with respect to the two (2) individuals and two (2) entities identified in this notice, pursuant to Executive Orders 13572 and 13582, are effective as of December 11, 2012.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions, Compliance & Evaluation, Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Avenue NW., (Treasury Annex), Washington, DC 20220, Tel.: 202/622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treas.gov/ofac*) or via facsimile through a 24-hour fax-on-demand service, Tel.: 202/622–0077.

Background

On December 11, 2012, the Director of OFAC, in consultation with the Department of State, designated pursuant to one or more of the criteria set forth in subsection 1(b) of Executive Order 13572, one (1) individual and one (1) entity.

The listings on OFAC's list of Specially Designated Nationals and Blocked Persons for the individual and entity, whose property and interests in property are blocked pursuant to Executive Order 13572, appear as follows:

Individual

1. JABER, Ayman (a.k.a. JABER, Aiman; a.k.a. JABER, Ayman Mehriz; a.k.a. JABER, Ayman Mohriz; a.k.a. JABIR, Ayman; a.k.a. JABIR, Ayman Muhriz); DOB 17 Jan 1967; Passport 003308607 (Syria) (individual) [SYRIA];

Entity

1. SHABIHA (a.k.a. AL–SHABBIHAH; a.k.a. SHABBIHA; a.k.a. SHABBIHAH; a.k.a. SHABEEHA), Syria [SYRIA].

On December 11, 2012, the Director of OFAC, in consultation with the Department of State, designated pursuant to one or more of the criteria set forth in subsection 1(b) of Executive Order 13582, two (2) individuals.

The listings on OFAC's list of Specially Designated Nationals and Blocked Persons for the individuals, whose property and interests in property are blocked pursuant to Executive Order 13582, appear as follows:

Individuals

1. JABER, Mohammad (a.k.a. JA FAR, Abu; a.k.a. JABIR, Mohammad; a.k.a. JABIR, Muhammad; a.k.a. JABIR, Muhammad Mahruz; a.k.a. JABIR, Muhammad Muhraz; a.k.a. JABIR, Muhammad Muhriz; a.k.a. JA'FAR, Abu); DOB 23 Jan 1957; POB Latakia, Syria; Passport N004871560 (Syria) (individual) [SYRIA].

2. JABER, Ayman (a.k.a. JABER, Aiman; a.k.a. JABER, Ayman Mehriz; a.k.a. JABER, Ayman Mohriz; a.k.a. JABIR, Ayman; a.k.a. JABIR, Ayman

Muhriz); DOB 17 Jan 1967; Passport 003308607 (Syria) (individual) [SYRIA]

On December 11, 2012, the Director of OFAC identified two (2) entities as falling within the definition of the Government of Syria set forth in section 8(d) of Executive Order 13582. On July 13, 2013, the Director of OFAC supplemented the identification information for JAYSH AL–SHA'BI.

The listings on OFAC's list of Specially Designated Nationals and Blocked Persons for the entities, whose property and interests in property are blocked, are as follows.

Entities

1. JAYSH AL–SHA'BI (a.k.a. AL–SHA'BI COMMITTEES; a.k.a. JAYSH AL–SHAAB; a.k.a. JISH SHAABI; a.k.a. SHA'BI COMMITTEES; a.k.a. SHA'BI FORCE; a.k.a. SYRIAN NATIONAL DEFENSE FORCE; a.k.a. SYRIAN NATIONAL DEFENSE FORCES; a.k.a. ''ARMY OF THE PEOPLE''; a.k.a. ''PEOPLE'S ARMY''; a.k.a. ''POPULAR COMMITTEES''; a.k.a. ''POPULAR FORCES''; a.k.a. ''SHA'BI''; a.k.a. ''THE POPULAR ARMY'') [SYRIA].

2. SHABIHA (a.k.a. AL–SHABBIHAH; a.k.a. SHABBIHA; a.k.a. SHABBIHAH; a.k.a. SHABEEHA), Syria [SYRIA].

Dated: July 11, 2013.

Adam Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2013–17135 Filed 7–18–13; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Publication of Iran General License D

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice, publication of general license.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is publishing General License D issued under the Iranian transactions sanctions program on May 30, 2013. General License D authorizes the exportation and reexportation to persons in Iran of certain services, software, and hardware incident to the exchange of personal communications, subject to certain limitations.

DATES: *Effective Date:* May 30, 2013.

FOR FURTHER INFORMATION CONTACT: Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490, Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Policy, tel.: 202–622–2746, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202–622–2410, Office of the General Counsel, Department of the Treasury, Washington, DC 20220 (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs also is available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Background

On May 30, 2013, OFAC issued General License D under the Iranian transactions sanctions program. At the time of its issuance on May 30, 2013, OFAC made General License D available on the OFAC Web site (*www.treasury.gov/ofac*). With this notice, OFAC is publishing General License D in the **Federal Register.**

GENERAL LICENSE D

General License With Respect to the Exportation and Reexportation of Certain Services, Software, and Hardware Incident to the Exchange of Personal Communications

(a) Effective May 30, 2013, to the extent that such transactions are not exempt from the prohibitions of the Iranian Transactions and Sanctions Regulations, 31 CFR part 560 (''ITSR''), and subject to the restrictions set forth in paragraph (b), the following transactions are authorized:

(1) The exportation or reexportation, directly or indirectly, from the United States or by U.S. persons, wherever located, to persons in Iran of fee-based services incident to the exchange of personal communications over the Internet, such as instant messaging, chat and email, social networking, sharing of photos and movies, web browsing, and blogging.

(2) The exportation or reexportation, directly or indirectly, from the United States or by U.S. persons, wherever located, to persons in Iran of fee-based software subject to the Export Administration Regulations, 15 CFR parts 730 through 774 (the ''EAR''), that is necessary to enable the services described in paragraph (a)(1), provided that such software is designated as EAR99 under the EAR, or is classified by the U.S. Department of Commerce on the Commerce Control List, 15 CFR part 774, supplement No. 1 (''CCL'') under export control classification number (''ECCN'') 5D992.c.

NOTE TO PARAGRAPHS (a)(1) AND (a)(2): *See* 31 CFR § 560.540 for provisions relating to the exportation to persons in Iran of publicly available, no-cost services incident to the exchange of personal communications over the Internet and publicly available, no-cost software necessary to enable such services.

(3) To the extent not authorized by paragraph (a)(2), the exportation or reexportation, directly or indirectly, from the United States or by U.S. persons, wherever located, to persons in Iran of certain software and hardware that are subject to the EAR and incident to personal communications, as well as related services, as specified in the Annex to this general license.

(4) The exportation or reexportation, directly or indirectly, from the United States or by U.S. persons, wherever located, to persons in Iran of consumer-grade Internet connectivity services and the provision, sale, or leasing of capacity on telecommunications transmission facilities (such as satellite or terrestrial network connectivity) incident to personal communications.

Note to Paragraph (a): The authorization set forth in paragraph (a) of this general license extends to entities owned or controlled by a United States person and established or maintained outside the United States subject to the conditions set forth in 31 CFR § 560.556. Nothing in this general license relieves the exporter from compliance with the export license application requirements of another Federal agency.

(b) This general license does not authorize:

(1) The exportation or reexportation, directly or indirectly, of the services, software, or hardware specified in paragraph (a) of this general license with knowledge or reason to know that such services, software, or hardware are intended for the Government of Iran.

(2) The exportation or reexportation, directly or indirectly, of the services, software, and hardware specified in paragraph (a) of this general license to any person whose property and interests in property are blocked pursuant to any part of 31 CFR chapter V.

(3) The exportation or reexportation, directly or indirectly, of commercial-grade Internet connectivity services or telecommunications transmission facilities (such as dedicated satellite links or dedicated lines that include quality of service guarantees).

(4) The exportation or reexportation, directly or indirectly, of web-hosting services that are for purposes other than personal communications (e.g., web-hosting services for commercial

endeavors) or of domain name registration services.

(c) Effective May 30, 2013, transfers of funds from Iran or for or on behalf of a person in Iran in furtherance of an underlying transaction authorized by paragraph (a) of this general license may be processed by U.S. depository institutions and U.S. registered brokers or dealers in securities so long as they are consistent with 31 CFR § 560.516.[1]

(d) Specific licenses may be issued on a case-by-case basis for the exportation and reexportation of services, software, and hardware incident to personal communications not specified in paragraph (a) or the Annex to this general license.

Issued: May 30, 2013.

ANNEX—SERVICES, SOFTWARE, AND HARDWARE INCIDENT TO PERSONAL COMMUNICATIONS AUTHORIZED FOR EXPORTATION AND REEXPORTATION TO IRAN BY PARAGRAPH (a) OF ITSR GENERAL LICENSE D

1.) ...	Mobile phones (including but not limited to smartphones), Personal Digital Assistants (PDAs), Subscriber Identity Module (SIM) cards designated EAR99 or classified on the CCL under ECCN 5A992.c; drivers and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.
2.) ...	Satellite phones and Broadband Global Area Network (BGAN) hardware designated EAR99 or classified under ECCN 5A992.c; demand drivers and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.
3.) ...	Modems, network interface cards, radio equipment (including antennaes), routers, switches, and WiFi access points, designed for 50 or fewer concurrent users, designated EAR99 or classified under ECCNs 5A992.c, 5A991.b.2, or 5A991.b.4; drivers, communications, and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.
4.) ...	Residential consumer satellite receive-only terminals, receiver equipment (including but not limited to antennaes, receivers, set-top boxes and video decoders) designated EAR99 or classified under ECCNs 5A992.c, 5A991.b.2 or 5A991.b.4; drivers, communications, and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.
5.) ...	Laptops, tablets, and personal computing devices, disk drives, data storage devices, computer peripherals, keyboards, and mice designated EAR99 or classified on the CCL under ECCNs 5A992.c, 5A991.b.2, 5A991.b.4 or 4A994.b; computer operating systems, and software required for effective consumer use of such hardware, including software updates and patches, designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.
6.) ...	Anti-virus and anti-malware software designated EAR99 or classified under ECCN 5D992.c, and services necessary for the operation of such software.
7.) ...	Anti-tracking software designated EAR99 or classified under ECCN 5D992.c, and services necessary for the operation of such software.
8.) ...	Mobile operating systems, online app stores, and related software designated EAR99 or classified under ECCN 5D992.c, and services necessary for the operation of such software.
9.) ...	Anti-censorship tools and related software designated EAR99 or classified under ECCN 5D992.c, and services necessary for the operation of such software.
10.)	Virtual Private Networks, proxy tools, and fee-based personal communications tools including voice, text, video, voice-over-IP telephony, video chat, and successor technologies, and communications and connectivity software required for effective consumer use designated EAR99 or classified under ECCN 5D992.c, and services necessary for the operation of such software.
11.)	Secure Sockets Layers (SSLs) designated EAR99 or classified under ECCN 5D992.c, and services necessary for the operation of such software.

Dated: July 10, 2013.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2013–17359 Filed 7–18–13; 8:45 am]

BILLING CODE 4810–AL–P

[1] The authorization set forth in paragraph (c) of this general license does not authorize any transaction prohibited by any part of chapter V of 31 CFR other than part 560. Accordingly, the transfer of funds may not be by, to, or through any of the following: (1) A person whose property and interests in property are blocked pursuant to the Weapons of Mass Destruction Proliferators Sanctions Regulations, 31 CFR part 544, or the Global Terrorism Sanctions Regulations, 31 CFR part 594; or (2) a person whose property and interests in property are blocked pursuant to any other part of 31 CFR chapter V, or any Executive order, except an Iranian financial institution whose property and interests in property are blocked solely pursuant to 31 CFR part 560.

FEDERAL REGISTER

Vol. 78 Friday,

No. 139 July 19, 2013

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 423, and 425

[CMS–1600–P]

RIN 0938–AR56

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2013.

ADDRESSES: In commenting, please refer to file code CMS–1600–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions for ''submitting a comment.''

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1600–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1600–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Chava Sheffield, (410) 786–2298, for issues related to practice expense methodology and impacts.

Ryan Howe, (410) 786–3355, for issues related to direct practice expense inputs and telehealth services.

Joanna Baldwin, (410) 786–7205, for issues related to misvalued services.

Ken Marsalek, (410) 786–4502, for issues related to the multiple procedure payment reduction.

Heidi Oumarou, (410) 786–7942, for issues related to the revision of Medicare Economic Index (MEI).

Roberta Epps, (410) 786–4503, for issues related to chiropractors billing for evaluation and management services.

Craig Dobyski, (410) 786–4584, for issues related to geographic practice cost indices.

Simone Dennis, (410) 786–8409, for issues related to therapy caps.

Darlene Fleischmann, (410) 786–2357, for issues related to ''incident to'' services.

Corinne Axelrod, (410) 786–5620, for issues related to ''incident to'' services in Rural Health Center s or Federally Qualified Health Centers.

Anne Tayloe-Hauswald, (410) 786–4546, for issues related to ambulance fee schedule and clinical lab fee schedule.

Sandra Adams, (410) 786–2982, for issues related to Medicare shared savings program.

Rashaan Byers, (410) 786–2305, for issues related to physician compare.

Christine Estella, (410) 786–0485, for issues related to the physician quality reporting system and EHR incentive program.

Ronke Fabayo, (410) 786–4460 or Jay Blake, (410) 786–9371, for issues related to individual liability for payments made to providers and suppliers and handling of incorrect payments.

Rosemarie Hakim, (410) 786–3934, for issues related to coverage of items and services furnished in FDA-approved investigational device exemption clinical trials.

Jamie Hermansen, (410) 786–2064 or Jyme Schafer, (410) 786–4643, for issues related to ultrasound screening for abdominal aortic aneurysms.

Pauline Lapin, (410)786–6883, for issues related to the chiropractic services demonstration budget neutrality issue.

Andrew Morgan, (410) 786–2543, for issues related to e-prescribing under Medicare Part D.

Michael Wrobleswki, (410) 786–4465, for issues related to value-based modifier and improvements to physician feedback.

Elliot Isaac, (410) 786–4735, for malpractice RVUs and for any physician payment issue not identified above.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Table of Contents

Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

AMA RUC American Medical Association/[Specialty Society] Relative [Value] Update Committee
ATRA American Taxpayer Relief Act (Pub. L. 112–240)
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
CAH Critical access hospital
CF Conversion factor
CPT [Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2012 American Medical Association. All rights reserved.*)
CY Calendar year
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
eRx Electronic prescribing
FFS Fee-for-service
FR **Federal Register**
GPCI Geographic practice cost index
HCPCS Healthcare Common Procedure Coding System
MCTRJCA Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96)
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multi-Factor Productivity
MIEA–TRHCA The Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act (Pub. L. 109–432)
MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110–275)
MP Malpractice
MPPR Multiple procedure payment reduction
MMEA Medicare and Medicaid Extenders Act (Pub. L. 111–309)
MMSEA Medicare, Medicaid, and State Children's Health Insurance Program Extension Act (Pub. L. 110–73)
NPP Nonphysician practitioner
OBRA '89 Omnibus Budget Reconciliation Act of 1989
OBRA '90 Omnibus Budget Reconciliation Act of 1990
PC Professional component
PE Practice expense
PE/HR Practice expense per hour
PFS Physician Fee Schedule
PQRS Physician Quality Reporting System
RFA Regulatory Flexibility Act
RIA Regulatory impact analysis
RVU Relative value unit
SGR Sustainable growth rate
TAP Technical Advisory Panel
TC Technical component
TPTCCA Temporary Payroll Tax Cut Continuation Act (Pub. L. 112–78)
VBP Value-based purchasing

Addenda Available Only Through the Internet on the CMS Web Site

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule with comment period are available through the Internet on the CMS Web site at *http://www.cms.gov/PhysicianFeeSched/*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2014 PFS proposed rule, refer to item CMS–1600–P. Readers who experience any problems accessing any of the Addenda or other documents referenced in this proposed rule and posted on the CMS Web site identified above should contact Elliot Isaac at (410) 786–4735.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2012 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major proposed rule would revise payment polices under the Medicare Physician Fee Schedule (PFS) and make other policy changes related to Medicare Part B payment. These changes would be applicable to services furnished in CY 2014.

2. Summary of the Major Provisions

The Social Security Act (Act) requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The Act requires that RVUs be established for three categories of resources: work, practice expense (PE); and malpractice (MP) expense; and that we establish by regulation each year payment amounts for all physicians' services, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major proposed rule, we propose RVUs for CY 2014 for the PFS and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. In addition, this proposed rule includes discussions and proposals regarding:

- Misvalued PFS Codes.
- Telehealth Services.
- Applying Therapy Caps to Outpatient Therapy Services Furnished by CAHs.
- Requiring the Compliance with State law as a Condition of Payment for Services Furnished Incident to Physician and Other Practitioner Services.
- Revising the MEI based on MEI TAP Recommendations.

• Updating the Ambulance Fee Schedule regulations.
• Updating the—
++ Physician Compare Web site.
++ Physician Quality Reporting System.
++ Electronic Health Record (EHR) Incentive Program.
++ Medicare Shared Savings Program.
• Budget Neutrality for the Chiropractic Services Demonstration.
• Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program.

3. Summary of Costs and Benefits

The Act requires that annual adjustments to PFS RVUs not cause annual estimated expenditures to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to RVUs would cause expenditures to change by more than $20 million, we must make adjustments to preserve budget neutrality. These adjustments can affect the distribution of Medicare expenditures across specialties. In addition, several proposed changes would affect the specialty distribution of Medicare expenditures. For most specialties the projected impacts are a small percentage change in Medicare payments under the PFS. For a few specialties a larger impact is projected. Diagnostic Testing Facilities, Independent Laboratory, Pathology, Radiation Oncology, and Radiation Therapy Centers are projected to have a change of 5 percent or more.

B. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, ''Payment for Physicians' Services.'' The system relies on national relative values that are established for work, PE, and MP, which are then adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the RVUs into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239, enacted on December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90 (Pub. L. 101–508, enacted on November 5, 1990). The final rule published on November 25, 1991 (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners who are permitted to bill Medicare under the PFS for services furnished to Medicare beneficiaries.

1. Development of the Relative Values

a. Work RVUs

The physician work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original physician work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

We establish work RVUs for new and revised codes based, in part, on our review of recommendations received from the American Medical Association/Specialty Society Relative Value Update Committee (AMA RUC).

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs. Originally, this new method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted on August 5, 1997) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in a final rule, published November 2, 1998 (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: the Clinical Practice Expert Panel (CPEP) data and the AMA's Socioeconomic Monitoring System (SMS) data. (These data sources are described in greater detail in the CY 2012 final rule with comment period (76 FR 73033).)

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some costs are borne by the facility. Medicare's payment to the facility (such as the OPPS payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those facility resources is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, enacted on November 29, 1999) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year

transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on malpractice insurance premium data collected from commercial and physician-owned insurers from all the states, the District of Columbia, and Puerto Rico.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review all RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed Five-Year Reviews of Work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

While refinements to the direct PE inputs initially relied heavily on input from the AMA RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

With regard to MP RVUs, we completed Five-Year Reviews of MP that were effective in CY 2005 and CY 2010.

In addition to the Five-Year Reviews, beginning for CY 2009, CMS and the AMA RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, which requires the agency to periodically identify, review and adjust values for potentially misvalued codes with an emphasis on seven specific categories (see section II.B.2. of this proposed rule).

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VI.C.1. of this proposed rule, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs would cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each physicians' service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of physician work, PE, and MP in an area compared to the national average costs for each component. (See section II.E.2 of this proposed rule for more information about GPCIs.)

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The CF for a given year is calculated using (a) the productivity-adjusted increase in the Medicare Economic Index (MEI) and (b) the Update Adjustment Factor (UAF), which is calculated by taking into account the Medicare Sustainable Growth Rate (SGR), an annual growth rate intended to control growth in aggregate Medicare expenditures for physicians' services, and the allowed and actual expenditures for physicians' services. A more detailed discussion of the calculation of the CF, the SGR, and the MEI appears in the PFS final rule with comment period for each calendar year (the most recent begins on 77 FR 69131).

The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU MP} \times \text{GPCI MP})] \times \text{CF}$$

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia conversion factor, in a manner to assure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate conversion factor for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

4. Most Recent Changes to the Fee Schedule

The CY 2013 PFS final rule with comment period (77 FR 68892) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized many of the CY 2012 interim RVUs and established interim RVUs for new and revised codes for CY 2013 to ensure that our payment system is updated to reflect changes in medical practice, coding changes, and the relative values of services. It also implemented certain statutory provisions including provisions of the Affordable Care Act (Pub. L. 111–148) and the Middle Class Tax Relief and Jobs Creation Act (MCTRJCA) (Pub. L. 112–96), including claims-based data reporting requirements for therapy services.

In the CY 2013 PFS final rule with comment period, we announced the following for CY 2013: The total PFS update of -26.5 percent; the initial estimate for the sustainable growth rate (SGR) of -19.7 percent; and the CY 2013 CF of $25.0008. These figures were calculated based on the statutory provisions in effect on November 1, 2012, when the CY 2013 PFS final rule with comment period was issued.

On January 2, 2013, the American Taxpayer Relief Act (ATRA) of 2012 (Pub. L. 112–240) was signed into law. Section 601(a) of the ATRA specified a zero percent update to the PFS CF for CY 2013. As a result, the CY 2013 PFS conversion factor was revised to $34.0320. In addition, the ATRA extended and added several provisions affecting Medicare services furnished in CY 2013, including:

- Section 602—extending the 1.0 floor on the work geographic practice cost index through CY 2013;
- Section 603—extending the exceptions process for outpatient therapy caps through CY 2013, extending the application of the cap and manual medical review threshold to services furnished in the hospital outpatient department (OPD) through CY 2013, and requiring the counting of a proxy amount for therapy services

furnished in a Critical Access Hospital (CAH) toward the cap and threshold during CY 2013.

In addition to the changes effective for CY 2013, section 635 of ATRA revised the equipment utilization rate assumption for advanced imaging services furnished on or after January 1, 2014.

On March 5, 2013, we submitted to the Medicare Payment Advisory Committee (MedPAC) an estimate of the SGR and CF applicable to Medicare payments for physicians' services for CY 2014, as required by section 1848(d)(1)(E) of the Act. The actual values used to compute physician payments for CY 2014 will be based on later data and are scheduled to be published by November 1, 2013 as part of the CY 2014 PFS final rule with comment period.

II. Provisions of the Proposed Rule for PFS

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. Section 121 of the Social Security Amendments of 1994 (Pub. L. 103–432), enacted on October 31, 1994, amended section 1848(c)(2)(C)(ii) of the Act to require us to develop a methodology for a resource-based system for determining PE RVUs for each physician's service. We develop PE RVUs by looking at the direct and indirect physician practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. In addition, we note that section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs for a year may not cause total PFS payments to differ by more than $20 million from what they would have otherwise been if the adjustments were not made. Therefore, if revisions to the RVUs cause expenditures to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, equipment, and supplies) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are based on our review of recommendations received from the AMA RUC. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units Under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period (75 percent old/25 percent new for CY 2010, 50 percent old/50 percent new for CY 2011, 25 percent old/75 percent new for CY 2012, and 100 percent new for CY 2013) from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete in CY 2013. Therefore, the CY 2014 PE RVUs are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the MEI to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

We do not use the PPIS data for sleep medicine since there is not a full year of Medicare utilization data for that specialty given the specialty code was only available beginning in October 1, 2012. We anticipate using the PPIS data to create PE/HR for sleep medicine for CY 2015 when we will have a full year of data to make the calculations.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS

for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable x-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other with respect to physician time.

For registered dietician services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to the ''All Physicians'' PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183).

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, equipment, and supplies) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Section II.A.2.b. of this proposed rule describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the physician work RVUs. We also incorporated the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is described as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. In other words, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that furnished the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example the initial indirect allocator would equal 6.00, resulting in a total PE RVUs of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Next, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

d. Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a hospital or facility setting, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. Because in calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service in a facility, the facility PE RVUs are generally lower than the nonfacility PE RVUs. Medicare makes a separate payment to the facility for its costs of furnishing a service.

e. Services With Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a ''global'' service. When services have PC and TC components that can be billed separately, the payment for the global service equals the sum of the payment for the TC and PC. This is a result of using a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global under the bottom-up methodology.)

f. PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746).

(1) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(2) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service. Apply a scaling adjustment to the direct inputs.

Step 2: Calculate the current aggregate pool of direct PE costs. This is the product of the current aggregate PE (aggregate direct and indirect) RVUs, the CF, and the average direct PE percentage from the survey data.

Step 3: Calculate the aggregate pool of direct costs. This is the sum of the product of the direct costs for each service from Step 1 and the utilization data for that service. For CY 2014, we adjusted the direct cost pool to match the new PE share of the MEI, as discussed in section II.D. of this rule.

Step 4: Using the results of Step 2 and Step 3 calculate a direct PE scaling adjustment so that the aggregate direct cost pool does not exceed the current aggregate direct cost pool and apply it to the direct costs from Step 1 for each service.

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs, as long as the same CF is used in Step 2 and Step 5. Different CFs will result in different direct PE scaling factors, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling factors offset one another.

(3) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical PE RVUs; and the work RVUs. For most services the indirect allocator is: Indirect percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs.

Note: For global services, the indirect allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.

For presentation purposes in the examples in Table 5, the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the current aggregate pool of PE RVUs by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service. For CY 2014, we adjusted the indirect cost pool to match the new PE share of the MEI, as discussed in section II.D. of this rule.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (**Note:** For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(4) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 6 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment and the MEI revision adjustment.

The final PE BN adjustment is calculated by comparing the results of Step 18 to the current pool of PE RVUs (prior to the MEI revision adjustment and the OPPS/ASC cap redistribution). This final BN adjustment is required to redistribute RVUs from step 18 to all PE RVUs in the PFS, and because certain specialties are excluded from the PE RVU calculation for ratesetting purposes, but all specialties are included for purposes of calculating the final BN adjustment. (See ''Specialties excluded from ratesetting calculation'' later in this section.) As discussed in section II.D. of this proposed rule, we are revising the Medicare Economic Index (MEI) for CY 2014.

Step 19: Consistent with the proposed policy addressed in section II.A.4. of this proposed rule, apply the OPPS/ASC cap to codes subject to the cap and redistribute the RVU reduction to the PE RVUs for all other services.

(5) Setup File Information

- *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain nonphysician practitioners paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthestist.
57	Individual certified prosthetist-orthotist.
58	Individuals not included in 55, 56, or 57.
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (e.g., drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
95	Competitive Acquisition Program (CAP) Vendor.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
1	Supplier of oxygen and/or oxygen related equipment.
2	Pedorthic personnel.
3	Medical supply company with pedorthic personnel.

• *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services, but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

• *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the physician time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80, 81, 82	Assistant at Surgery	16%	Intraoperative portion.
AS	Assistant at Surgery—Physician Assistant	14% (85% * 16%)	Intraoperative portion.
50 or LT and RT	Bilateral Surgery	150%	150% of physician time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES—Continued

Modifier	Description	Volume adjustment	Time adjustment
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPR). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since the average allowed charge is used when simulating RVUs, and therefore, includes all adjustments. A time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where time units are duplicative.

- *Work RVUs:* The setup file contains the work RVUs from this proposed rule with comment period.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

*(1/(minutes per year * usage)) * price * ((interest rate/(1-(1/((1 + interest rate)∧ life of equipment)))) + maintenance)*

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.

usage = variable, see discussion below.

price = price of the particular piece of equipment.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

interest rate = variable, see discussion below.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment. For expensive diagnostic imaging equipment, which is equipment priced at over $1 million (for example, computed tomography (CT) and magnetic resonance imaging (MRI) scanners), we use an equipment utilization rate assumption of 75 percent. Section 1848(b)(4)(C) of the Act, as modified by section 635 of the America Taxpayer Relief Act of 2012 (Pub. L. 112–240, enacted on January 2, 2013) (ATRA), requires that for fee schedules established for CY 2014 and subsequent years, in the methodology for determining PE RVUs for expensive diagnostic imaging equipment, the Secretary shall use a 90 percent assumption. The provision also requires that the reduced expenditures attributable to this change in the utilization rate for CY 2014 and subsequent years shall not be taken into account when applying the BN limitation on annual adjustments described in section 1848(c)(2)(B)(ii)(II) of the Act. We are applying the 90 percent utilization rate assumption in CY 2014 to all of the services to which the 75 percent equipment utilization rate assumption applied in CY 2013. These services are listed in a file called ''CY 2014 CPT Codes Subject to 90 Percent Usage Rate,'' available on the CMS Web site under downloads for the CY 2014 PFS proposed rule at *http://www.cms.gov/physicianfeesched/downloads/*. These codes are also displayed in Table 3.

TABLE 3—CPT CODES SUBJECT TO 90 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION

CPT code	Short descriptor
70336 ..	Mri, temporomandibular joint(s).
70450 ..	Ct head/brain w/o dye.
70460 ..	Ct head/brain w/dye.
70470 ..	Ct head/brain w/o & w/dye.
70480 ..	Ct orbit/ear/fossa w/o dye.
70481 ..	Ct orbit/ear/fossa w/dye.
70482 ..	Ct orbit/ear/fossa w/o & w/dye.
70486 ..	Ct maxillofacial w/o dye.
70487 ..	Ct maxillofacial w/dye.
70488 ..	Ct maxillofacial w/o & w/dye.
70490 ..	Ct soft tissue neck w/o dye.
70491 ..	Ct soft tissue neck w/dye.
70492 ..	Ct soft tissue neck w/o & w/dye.
70496 ..	Ct angiography, head.
70498 ..	Ct angiography, neck.
70540 ..	Mri orbit/face/neck w/o dye.
70542 ..	Mri orbit/face/neck w/dye.
70543 ..	Mri orbit/face/neck w/o & w/dye.
70544 ..	Mr angiography head w/o dye.
70545 ..	Mr angiography head w/dye.
70546 ..	Mr angiography head w/o & w/dye.

TABLE 3—CPT CODES SUBJECT TO 90 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION—Continued

CPT code	Short descriptor
70547 ..	Mr angiography neck w/o dye.
70548 ..	Mr angiography neck w/dye.
70549 ..	Mr angiography neck w/o & w/dye.
70551 ..	Mri brain w/o dye.
70552 ..	Mri brain w/dye.
70553 ..	Mri brain w/o & w/dye.
70554 ..	Fmri brain by tech.
71250 ..	Ct thorax w/o dye.
71260 ..	Ct thorax w/dye.
71270 ..	Ct thorax w/o & w/dye.
71275 ..	Ct angiography, chest.
71550 ..	Mri chest w/o dye.
71551 ..	Mri chest w/dye.
71552 ..	Mri chest w/o & w/dye.
71555 ..	Mri angio chest w/or w/o dye.
72125 ..	CT neck spine w/o dye.
72126 ..	Ct neck spine w/dye.
72127 ..	Ct neck spine w/o & w/dye.
72128 ..	Ct chest spine w/o dye.
72129 ..	Ct chest spine w/dye.
72130 ..	Ct chest spine w/o & w/dye.
72131 ..	Ct lumbar spine w/o dye.
72132 ..	Ct lumbar spine w/dye.
72133 ..	Ct lumbar spine w/o & w/dye.
72141 ..	Mri neck spine w/o dye.
72142 ..	Mri neck spine w/dye.
72146 ..	Mri chest spine w/o dye.
72147 ..	Mri chest spine w/dye.
72148 ..	Mri lumbar spine w/o dye.
72149 ..	Mri lumbar spine w/dye.
72156 ..	Mri neck spine w/o & w/dye.
72157 ..	Mri chest spine w/o & w/dye.
72158 ..	Mri lumbar spine w/o & w/dye.
72159 ..	Mr angio spone w/o&w/dye.
72191 ..	Ct angiography, pelv w/o & w/dye.
72192 ..	Ct pelvis w/o dye.
72193 ..	Ct pelvis w/dye.
72194 ..	Ct pelvis w/o & w/dye.
72195 ..	Mri pelvis w/o dye.
72196 ..	Mri pelvis w/dye.
72197 ..	Mri pelvis w/o &w/dye.
72198 ..	Mri angio pelvis w/or w/o dye.
73200 ..	Ct upper extremity w/o dye.
73201 ..	Ct upper extremity w/dye.
73202 ..	Ct upper extremity w/o & w/dye.
73206 ..	Ct angio upper extr w/o & w/dye.
73218 ..	Mri upper extr w/o dye.
73219 ..	Mri upper extr w/dye.
73220 ..	Mri upper extremity w/o & w/dye.
73221 ..	Mri joint upper extr w/o dye.
73222 ..	Mri joint upper extr w/dye.
73223 ..	Mri joint upper extr w/o & w/dye.
73225 ..	Mr angio upr extr w/o&w/dye.
73700 ..	Ct lower extremity w/o dye.
73701 ..	Ct lower extremity w/dye.

TABLE 3—CPT CODES SUBJECT TO 90 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION—Continued

CPT code	Short descriptor
73702 ..	Ct lower extremity w/o & w/dye.
73706 ..	Ct angio lower ext w/o & w/dye.
73718 ..	Mri lower extremity w/o dye.
73719 ..	Mri lower extremity w/dye.
73720 ..	Mri lower ext w/& w/o dye.
73721 ..	Mri joint of lwr extre w/o dye.
73722 ..	Mri joint of lwr extr w/dye.
73723 ..	Mri joint of lwr extr w/o & w/dye.
73725 ..	Mr angio lower ext w or w/o dye.
74150 ..	Ct abdomen w/o dye.
74160 ..	Ct abdomen w/dye.
74170 ..	Ct abdomen w/o & w/dye.
74174 ..	Ct angiography, abdomen and pelvis w/o & w/dye.
74175 ..	Ct angiography, abdom w/o & w/dye.
74176 ..	Ct abdomen and pelvis w/o dye.
74177 ..	Ct abdomen and pelvis w/dye.
74178 ..	Ct abdomen and pelvis w/and w/o dye.
74181 ..	Mri abdomen w/o dye.
74182 ..	Mri abdomen w/dye.
74183 ..	Mri abdomen w/o and w/dye.
74185 ..	Mri angio, abdom w/or w/o dye.
74261 ..	Ct colonography, w/o dye.
74262 ..	Ct colonography, w/dye.
75557 ..	Cardiac mri for morph.
75559 ..	Cardiac mri w/stress img.
75561 ..	Cardiac mri for morph w/dye.
75563 ..	Cardiac mri w/stress img & dye.
75565 ..	Card mri vel flw map add-on.
75571 ..	Ct hrt w/o dye w/ca test.

TABLE 3—CPT CODES SUBJECT TO 90 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION—Continued

CPT code	Short descriptor
75572 ..	Ct hrt w/3d image.
75573 ..	Ct hrt w/3d image, congen.
75574 ..	Ct angio hrt w/3d image.
75635 ..	Ct angio abdominal arteries.
76380 ..	CAT scan follow up study.
77058 ..	Mri, one breast.
77059 ..	Mri, broth breasts.
77078 ..	Ct bone density, axial.
77084 ..	Magnetic image, bone marrow.

Interest Rate: In the CY 2013 final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation. The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table 4. See 77 FR 68902 for a thorough discussion of this issue.

TABLE 4—SBA MAXIMUM INTEREST RATES

Price	Useful life	Interest rate (percent)
<$25K	<7 Years	7.50

TABLE 4—SBA MAXIMUM INTEREST RATES—Continued

Price	Useful life	Interest rate (percent)
$25K to $50K	<7 Years	6.50
>$50K	<7 Years	5.50
<$25K	7+ Years	8.00
$25K to $50K	7+ Years	7.00
>$50K	7+ Years	6.00

See 77 FR 68902 for a thorough discussion of this issue.

TABLE 5—CALCULATION OF PE RVUS UNDER METHODOLOGY FOR SELECTED CODES

	Step	Source	Formula	99213 Office visit, est non-facility	33533 CABG, arterial, single facility	71020 Chest x-ray non-facility	71020–TC Chest x-ray non-facility	71020–26 Chest x-ray non-facility	93000 ECG, complete non-facility	93005 ECG, tracing non-facility	93010 ECG, report non-facility
(1) Labor cost (Lab)	Step 1	AMA		13.32	77.52	5.74	5.74	0.00	6.12	6.12	0.00
(2) Supply cost (Sup)	Step 1	AMA		2.98	0.00	3.39	3.39	0.00	1.19	1.19	0.00
(3) Equipment cost (Eqp)	Step 1	AMA		0.17	0.58	7.24	7.24	0.00	0.11	0.11	0.00
(4) Direct cost (Dir)	Step 1		=(1)+(2)+(3)	16.48	78.10	16.38	16.38	0.00	7.42	7.42	0.00
(5) Direct adjustment (Dir. Adj.).	Steps 2–4	See footnote*		0.5427	0.5427	0.5427	0.5427	0.5427	0.5427	0.5427	0.5427
(6) Adjusted Labor	Steps 2–4	=Labor * Dir Adj	=(1)*(5)	7.23	42.07	3.11	3.11	0.00	3.32	3.32	0.00
(7) Adjusted Supplies	Steps 2–4	=Eqp * Dir Adj	=(2)*(5)	1.62	0.00	1.84	1.84	0.00	0.65	0.65	0.00
(8) Adjusted Equipment	Steps 2–4	=Sup * Dir Adj	=(3)*(5)	0.09	0.32	3.93	3.93	0.00	0.06	0.06	0.00
(9) Adjusted Direct	Steps 2–4		=(6)+(7)+(8)	8.94	42.39	8.89	8.89	0.00	4.03	4.03	0.00
(10) Conversion Factor (CF)	Step 5	PFS		34.0230	34.0230	34.0230	34.0230	34.0230	34.0230	34.0230	34.0230
(11) Adj. labor cost converted.	Step 5	=(Lab * Dir Adj)/CF	=(6)/(10)	0.21	1.24	0.09	0.09	0.00	0.10	0.10	0.00
(12) Adj. supply cost converted.	Step 5	=(Sup * Dir Adj)/CF	=(7)/(10)	0.05	0.00	0.05	0.05	0.00	0.02	0.02	0.00
(13) Adj. equipment cost converted.	Step 5	=(Eqp * Dir Adj)/CF	=(8)/(10)	0.00	0.01	0.12	0.12	0.00	0.00	0.00	0.00
(14) Adj. direct cost converted.	Step 5		=(11)+(12)+(13)	0.26	1.25	0.26	0.26	0.00	0.12	0.12	0.00
(15) Work RVU	Setup File	PFS		0.97	33.75	0.22	0.00	0.22	0.17	0.00	0.17
(16) Dir_pct	Steps 6,7	Surveys		0.31	0.18	0.31	0.31	0.31	0.31	0.31	0.31
(17) Ind_pct	Steps 6,7	Surveys		0.69	0.82	0.69	0.69	0.69	0.69	0.69	0.69
(18) Ind. Alloc. Formula (1st part).	Step 8	See Step 8		((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)
(19) Ind. Alloc.(1st part)	Step 8		See 18	0.79	5.87	0.64	0.64	0.00	0.29	0.29	0.00
(20) Ind. Alloc. Formula (2nd part).	Step 8	See Step 8		(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)
(21) Ind. Alloc.(2nd part)	Step 8		See 20	0.97	33.75	0.31	0.09	0.22	0.27	0.10	0.17
(22) Indirect Allocator (1st + 2nd).	Step 8		=(19)+(21)	1.76	39.62	0.95	0.73	0.22	0.56	0.39	0.17
(23) Indirect Adjustment (Ind. Adj.).	Steps 9–11	See Footnote**		0.3826	0.3826	0.3826	0.3826	0.3826	0.3826	0.3826	0.3826
(24) Adjusted Indirect Allocator.	Steps 9–11	=Ind Alloc * Ind Adj		0.67	15.16	0.36	0.28	0.08	0.21	0.15	0.07
(25) Ind. Practice Cost Index (IPCI).	Steps 12–16			1.08	0.77	0.93	0.93	0.93	0.91	0.91	0.91
(26) Adjusted Indirect	Step 17	= Adj.Ind Alloc * PCI	=(24)*(25)	0.73	11.60	0.34	0.26	0.08	0.19	0.14	0.06
(27) Pre-Cap PE RVU	Step 18	=(Adj Dir + Adj Ind) * Other Adj.	=((14)+(26)) * Other Adj)***	0.98	12.78	0.61	0.53	0.08	0.32	0.26	0.06
(28) OPPS/ASC Cap Adj	Step 19	PFS		1.016	1.016	1.016	1.016	1.016	1.016	1.016	1.016
(29) Final PE RVU	Step 19	PE RVU * OPPS/ASC Cap Adj.	(27)*(28)	1.00	12.99	0.62	0.54	0.08	0.32	0.26	0.06

Note: PE RVUs in Table 5, row 28, may not match Addendum B due to rounding.

*The direct adj = [current PE RVUs * CF * avg dir pct]/[sum direct inputs] = [Step 2]/[Step 3]

**The indirect adj = [current PE RVUs * avg ind pct]/[sum of ind allocators] = [Step 9]/[Step 10]

***The other adjustment includes adjustments for the changes in the equipment utilization rate for certain services and the MEI revisions.

Note: The use of any particular conversion factor (CF) in Table 5 to illustrate the PE calculation has no effect on the resulting RVUs.

3. Changes to Direct PE Inputs for Specific Services

In this section, we discuss other CY 2014 proposals and revisions related to direct PE inputs for specific services. The proposed revisions are included in the proposed rule CY 2014 direct PE database, which is available on the CMS Web site under the supporting data files for the CY 2014 PFS proposed rule with comment period at *www.cms.gov/PhysicianFeeSched/.*

a. Anomalous Supply Inputs

In the CY 2013 PFS final rule with comment period, we established interim final direct PE inputs based on acceptance, with refinement, of recommendations submitted by the AMA RUC. Although we generally address public comments on the prior year's interim final direct PE inputs in the following year's final rule with comment period, several commenters raised an issue regarding anomalous supply items that we believe is best addressed through proposed revisions to the direct PE inputs.

For the CY 2013 interim final direct PE inputs for a series of codes that describe six levels of surgical pathology services (CPT codes 88300, 88302, 88304, 88305, 88307, 88309), we did not accept the AMA RUC recommendation to create two new direct PE supply inputs because we did not consider these items to be disposable supplies (77 FR 69074). The recommended new items were called ''specimen, solvent, and formalin disposal cost,'' and ''courier transportation costs.'' In the CY 2013 PFS final rule with comment period, we explained that neither the specimen and supply disposal nor courier costs for transporting specimens are appropriately considered disposable medical supplies. Instead, we stated these costs are incorporated into the PE RVUs for these services through the indirect PE allocation. We also noted that the current direct PE inputs for these and similar services across the PFS do not include these kinds of costs as disposable supplies.

Several commenters noted that, contrary to our assertion in the final rule with comment period, there are a few items incorporated in the direct PE input database as ''supplies'' that are no more disposable supplies than the new items recommended by the AMA RUC for the surgical pathology codes. These commenters identified seven supply inputs in particular that they believe are analogous to the items that we did not accept in establishing CY 2013 interim final direct PE inputs. These items and their associated HCPCS codes are listed in Table 6.

TABLE 6—ITEMS IDENTIFIED BY COMMENTERS

CMS supply code	Item description	Associated CPT codes
SK106	device shipping cost	93271, 93229, 93268.
SK112	Federal Express cost (average across all zones)	64650, 88363, 64653.
SK113	communication, wireless per service	93229.
SK107	fee, usage, cycletron/accelerator, gammaknife, Lincac SRS System.	77423, 77422.
SK110	fee, image analysis	96102, 96101, 99174.
SK111	fee, licensing, computer, psychology	96102, 96101, 96103, 96120.
SD140	bag system, 1000ml (for angiography waste fluids)	93451, 93452, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461.

We reviewed each of these items for consistency with the general principles of the PE methodology regarding the consistent categorization of all costs. Within the PE methodology, all costs other than clinical labor, disposable supplies, and medical equipment are considered indirect costs. For six of the items contained in Table 6, we agree with the commenters that the items should not be considered disposable supplies. We believe that these items are more appropriately categorized as indirect PE costs, which are reflected in the allocation of indirect PE RVUs rather than direct PE. Therefore, we are proposing to remove the following six items from the direct PE input database for CY 2014: ''device shipping cost'' (SK106); ''Federal Express cost (average across all zones)'' (SK112); ''communication, wireless per service'' (SK113); ''fee, usage, cycletron/accelerator, gammaknife, Lincac SRS System'' (SK107); ''fee, image analysis'' (SK110); and ''fee, licensing, computer, psychology'' (SK111). The CY 2014 proposed direct PE input database and Addendum B of this proposed rule reflect these proposed revisions.

In the case of the supply item called ''bag system, 1000ml (for angiography waste fluids)'' (SD140), we do not agree with the commenters that this item is analogous to the specimen disposal costs recommended for the surgical pathology codes. This supply input represents only the costs of the disposable material items associated with the removal of waste fluids that typically result from a particular procedure. In contrast, the item recommended by the AMA RUC for surgical pathology consisted of an amortized portion of a specimen disposal contract that includes costs for resources such as labor and transportation. Furthermore, we do not believe that the specimen disposal contract is attributable to individual procedures within the established PE methodology. We believe that a disposable supply is one that is attributable, in its entirety, to an individual patient for a particular service. An amortized portion of a specimen disposal contract does not meet these criteria. Accordingly, as stated in the CY 2013 final rule with comment period, we did not accept the AMA RUC recommendation to create a new supply item related to specimen disposal costs. We believe that many physician offices and other nonfacility settings where Medicare beneficiaries receive services incur costs related to waste management or other service contracts, but none of these costs are currently incorporated into the PE methodology as disposable supplies. Instead, these costs are appropriately categorized as indirect costs and are reflected in the PE RVUs through the allocation of indirect PE. We are clarifying that we believe that supply costs related to specimen disposal attributable to individual services may be appropriately categorized as disposable supplies, but that specimen disposal costs related to an allocated portion of service contracts that cannot be attributed to individual services should not be incorporated into the direct PE input database as disposable supplies.

Moreover, because do not agree with commenters that the ''bag system, 1000ml (for angiography waste fluids)'' (SD140) is analogous to a specimen disposal contract for the reasons state above, we continue to believe that SD140 is a direct expense. Accordingly, we are not removing SD140 from the direct PE input database. Additionally, we anticipate responding to these and other aspects of the comments regarding the direct PE inputs for the surgical pathology services in the CY 2014 PFS final rule with comment period.

b. Direct PE Input Refinements based on Routine Data Review

In reviewing the direct PE input database, we have identified several discrepancies that we believe should be addressed for CY 2014. In the following paragraphs, we identify the nature of these discrepancies, the affected codes, and the refinements displayed in the CY 2014 proposed direct PE input database. As part of our internal review of information in the direct PE input database, we identified supply items that appeared without quantities for CPT code 51710 (Change of cystostomy tube; complicated). Upon reviewing these items we believe that the codes should include the items at the quantities listed in Table 7.

TABLE 7—SUPPLY ITEMS AND QUANTITIES FOR CPT CODE 51710

Supply code	Description of supply item	NF quantity
SA069	tray, suturing	1.0
SB007	drape, sterile barrier 16in x 29in.	1.0
SC029	needle, 18–27g	1.0
SC051	syringe 10–12ml	1.0
SD024	catheter, Foley	1.0
SD088	Guidewire	1.0
SF036	suture, nylon, 3–0 to 6–0, c.	1.0
SG055	gauze, sterile 4in x 4in	1.0
SG079	tape, surgical paper 1in (Micropore).	6.0
SH075	water, sterile inj	3.0
SJ032	lubricating jelly (K–Y) (5gm uou).	1.0

TABLE 7—SUPPLY ITEMS AND QUANTITIES FOR CPT CODE 51710—Continued

Supply code	Description of supply item	NF quantity
SJ041	povidone soln (Betadine)	20.0

Upon reviewing the direct PE inputs for CPT code 51710 and the related code 51705 (Change of cystostomy tube; simple), we also noted that the direct PE input database includes an anomalous 0.5 minutes of clinical labor time in the post-service period. We believe that this small portion of clinical labor time is the result of a rounding error in our data and should be removed from the direct PE input database.

During our review of the data, we noted an invalid supply code (SM037) that appears in the direct PE input database for CPT codes 88312 and 88313. Upon review of the code, we believe that the supply item called ''wipes, lens cleaning (per wipe) (Kimwipe)'' (SM027) should be included in the code instead of the invalid code. The CY 2014 proposed direct PE input database reflects these proposed revisions.

Additionally, we conducted a routine review of the codes valued in the nonfacility setting for which moderate sedation is inherent in the procedure. Consistent with the standard moderate sedation package finalized in the CY 2012 PFS final rule with comment period (76 FR 73043), we have made minor adjustments to the nurse time and equipment time of 18 of these codes. These codes appear in Table 8, and the CY 2014 proposed direct PE input database reflects the proposed refined inputs for moderation sedation.

TABLE 8—CODES WITH MINOR ADJUSTMENTS TO MODERATE SEDATION INPUTS

CPT code	Descriptor
31629	Bronchoscopy/needle bx each.
31645	Bronchoscopy clear airways.
31646	Bronchoscopy reclear airway.
32405	Percut bx lung/mediastinum.
32550	Insert pleural cath.
35471	Repair arterial blockage.
37183	Remove hepatic shunt (tips).
37210	Embolization uterine fibroid.
43453	Dilate esophagus.
43458	Dilate esophagus.
44394	Colonoscopy w/snare.
45340	Sig w/balloon dilation.
47000	Needle biopsy of liver.
47525	Change bile duct catheter.
49411	Ins mark abd/pel for rt perq.
50385	Change stent via transureth.
50386	Remove stent via transureth.
57155	Insert uteri tandem/ovoids.
93312	Echo transesophageal.
93314	Echo transesophageal.
G0341	Percutaneous islet celltrans.

c. Adjustments to Pre-Service Clinical Labor Minutes

We recently received a recommendation from the AMA RUC regarding appropriate pre-service clinical labor minutes in the facility setting for codes with 000 day global periods. In general, the AMA RUC has recommended that codes with 000 day global period include a maximum of 30 minutes of clinical labor time in the pre-service period in the facility setting. The AMA RUC identified 48 codes that currently include more clinical labor time than this recommended maximum and provided us with recommended pre-service clinical labor minutes in the facility setting of 30 minutes or fewer for these 48 codes. We reviewed the AMA RUC's recommendation and agree that the recommended reductions would be appropriate to maintain relativity with other 000 day global codes. Therefore, we propose to amend the pre-service clinical labor minutes for the codes listed in Table 9, consistent with the AMA RUC recommendation. The proposed CY 2014 direct PE input database reflects this proposal.

TABLE 9—000-DAY GLOBAL CODES WITH PROPOSED CHANGES TO PRE-SERVICE CL TIME

CPT code	Short descriptor	Existing CL pre-service facility minutes	Proposed CL pre-service facility minutes (AMA RUC recommendation)
20900	Removal of bone for graft	60	30
20902	Removal of bone for graft	60	30
33224	Insert pacing lead & connect	35	30
33226	Reposition l ventric lead	35	30
36800	Insertion of cannula	60	0
36861	Cannula declotting	37	0
37202	Transcatheter therapy infuse	45	0
50953	Endoscopy of ureter	60	30

TABLE 9—000-DAY GLOBAL CODES WITH PROPOSED CHANGES TO PRE-SERVICE CL TIME—Continued

CPT code	Short descriptor	Existing CL pre-service facility minutes	Proposed CL pre-service facility minutes (AMA RUC recommendation)
50955	Ureter endoscopy & biopsy	60	30
51726	Complex cystometrogram	41	30
51785	Anal/urinary muscle study	34	30
52250	Cystoscopy and radiotracer	37	30
52276	Cystoscopy and treatment	32	30
52277	Cystoscopy and treatment	37	30
52282	Cystoscopy implant stent	31	30
52290	Cystoscopy and treatment	31	30
52300	Cystoscopy and treatment	36	30
52301	Cystoscopy and treatment	36	30
52334	Create passage to kidney	31	30
52341	Cysto w/ureter stricture tx	42	30
52342	Cysto w/up stricture tx	42	30
52343	Cysto w/renal stricture tx	42	30
52344	Cysto/uretero stricture tx	55	30
52345	Cysto/uretero w/up stricture	55	30
52346	Cystouretero w/renal strict	55	30
52351	Cystouretero & or pyeloscope	45	30
52352	Cystouretero w/stone remove	50	30
52353	Cystouretero w/lithotripsy	50	30
52354	Cystouretero w/biopsy	50	30
52355	Cystouretero w/excise tumor	50	30
54100	Biopsy of penis	33	30
61000	Remove cranial cavity fluid	60	15
61001	Remove cranial cavity fluid	60	15
61020	Remove brain cavity fluid	60	15
61026	Injection into brain canal	60	15
61050	Remove brain canal fluid	60	15
61055	Injection into brain canal	60	15
61070	Brain canal shunt procedure	60	15
62268	Drain spinal cord cyst	36	30
67346	Biopsy eye muscle	42	30
68100	Biopsy of eyelid lining	32	30
93530	Rt heart cath congenital	35	30
93531	R & l heart cath congenital	35	30
93532	R & l heart cath congenital	35	30
93533	R & l heart cath congenital	35	30
93580	Transcath closure of asd	35	30
93581	Transcath closure of vsd	35	30

d. Price Adjustment for Laser Diode

It has come to our attention that the price associated with the equipment item called ''laser, diode, for patient positioning (Probe)'' (ER040) in the direct PE input database is $7,678 instead of $18,160 as listed in the CY 2013 PFS final rule with comment period (77 FR 68922). The CY 2014 proposed direct PE input database reflects the updated price for the equipment item.

e. Direct PE Inputs for Stereotactic Radiosurgery (SRS) Services (CPT Codes 77372 and 77373)

Since 2001, Medicare has used HCPCS G-codes, in addition to the CPT codes, for stereotactic radiosurgery (SRS) to distinguish robotic and non-robotic methods of delivery. Based on our review of the current SRS technology, it is our understanding that most services currently furnished with linac-based SRS technology, including services currently billed using the non-robotic codes, incorporate some type of robotic feature. Therefore, we believe that it is no longer necessary to continue to distinguish robotic versus non-robotic linac-based SRS through the HCPCS G-codes. For purposes of the hospital outpatient prospective payment system (OPPS), CMS is proposing to replace the existing four SRS HCPCS G-codes G0173 (Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session), G0251 (Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment), G0339 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment), and G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment), with the SRS CPT codes 77372 (Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based) and 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) that do not distinguish between robotic and non-robotic methods of delivery. We refer readers to section II.C.3 of the CY 2014 OPPS proposed rule for more discussion of that proposal. We also refer readers to the CY 2007 OPPS final rule (71 FR 68023 through 68026) for a

detailed discussion of the history of the SRS codes.

Two of the four current SRS G-codes are paid in the nonfacility setting through the PFS. These two codes, G0339 and G0340, describe robotic SRS treatment delivery and are contractor-priced. CPT codes 77372 and 77373, which describe SRS treatment delivery without regard to the method of delivery, are currently paid in the nonfacility setting based on resource-based RVUs developed through the standard PE methodology. If the CY 2014 OPPS proposal is implemented, it would appear that there would no longer be a need for G-codes to describe robotic SRS treatment and delivery. Prior to eliminating the contractor-priced G-codes and using the existing CPT code for PFS payment of services previously reported using G-codes, we believe that it would be appropriate to ensure that the direct PE inputs used to develop PE RVUs for CPT codes 77372 and 77373 accurately reflect the typical resources used in furnishing the services that would be reported in the non-facility setting in the absence of the robotic G-codes. Therefore, for CY 2014, we are not proposing to replace the contractor-priced G-codes for PFS payment. We are seeking comment from the public and stakeholders, including the AMA RUC, regarding whether or not the direct PE inputs for CPT codes 77372 and 77373 would continue to accurately estimate the resources used in furnishing typical SRS delivery were there no coding distinction between robotic and non-robotic methods of delivery.

3. Using OPPS and ASC Rates in Developing PE RVUs

As we explain in section II.A.2.d of this proposed rule, we typically establish two PE RVUs for procedures that can be furnished in either a nonfacility setting, like a physician's office, or facility setting, like a hospital. The nonfacility RVUs reflect all of the direct and indirect practice expenses of providing a particular service when the entire service is furnished in a nonfacility setting. The facility RVUs are designed to reflect the direct and indirect practice expenses typically associated with furnishing a particular service in a setting, such as a hospital or ASC where those facilities incur a portion or all of the costs. Thus, the difference between the facility and nonfacility RVUs is because Medicare makes a separate payment to the facility for its costs of furnishing a service when a service is furnished in a facility.

When services are furnished in the facility setting, such as a hospital outpatient department (OPD) or an ambulatory surgical center (ASC), the total Medicare payment (made to the facility and the professional combined) typically exceeds the Medicare payment made for the same service when furnished in the physician office or other nonfacility setting. We believe that this payment difference generally reflects the greater costs that facilities incur than those incurred by practitioners furnishing services in offices and other non-facility settings. For example, hospitals incur higher overhead costs because they maintain the capability to furnish services 24 hours a day and 7 days per week, furnish services to higher acuity patients than those who receive services in physician offices, and have additional legal obligations such as complying with the Emergency Medical Treatment and Active Labor Act (EMTALA). Additionally, hospitals and ASCs must meet Medicare conditions of participation and conditions for coverage, respectively.

However, we have found that for some services, the total Medicare payment when the service is furnished in the physician office setting exceeds the total Medicare payment when the service is furnished in an OPD or an ASC. When this occurs, we believe it is not the result of appropriate payment differentials between the services furnished in different settings. Rather, we believe it is due to anomalies in the data we use under the PFS and in the application of our resource-based PE methodology to the particular services.

The PFS PE RVUs rely heavily on the voluntary submission of information by individuals furnishing the service and who are paid at least in part based on the data provided. Currently, we have little means to validate whether the information is accurate or reflects typical resource costs. Furthermore, in the case of certain direct costs, like the price of high-cost disposable supplies and expensive capital equipment, even voluntary information has been very difficult to obtain. In some cases the PE RVUs are based upon single price quotes or one paid invoice. We have addressed these issues extensively in previous rulemaking (75 FR 73252) and again in section II.A.3.e of this proposed rule. Such incomplete, small sample, potentially biased or inaccurate resource input costs may distort the resources used to develop nonfacility PE RVUs used in calculating PFS payment rates for individual services.

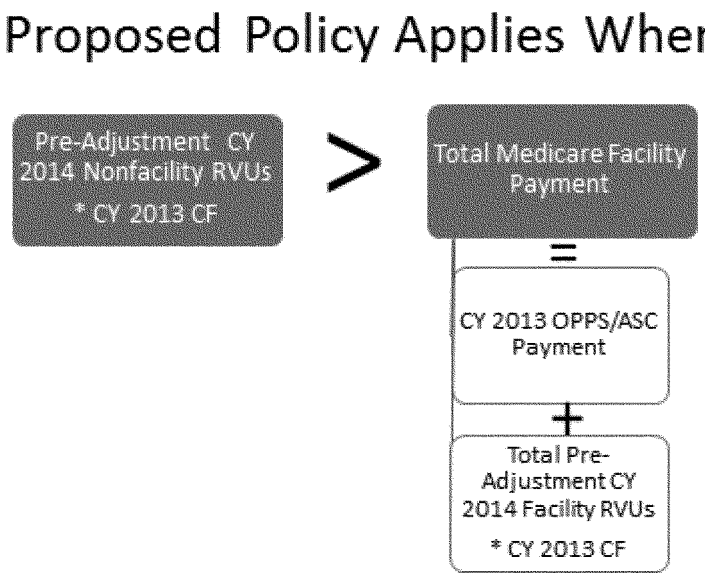
In addition to the accuracy issues with some of the physician PE resource inputs, the data used in the PFS PE methodology can often be outdated. As we have previously noted (77 FR 68921) there is no practical means for CMS or stakeholders to engage in a complete simultaneous review of the input resource costs for all HCPCS codes paid under the PFS on an annual or even regular basis. Thus, the information used to estimate PE resource costs for PFS services is not routinely updated. Instead, we strive to maintain relativity by reviewing the work RVUs, physician time, and direct PE inputs for a code at the same time and reviewing all codes within families where appropriate. Nonetheless, outdated resource input costs may distort RVUs used to develop nonfacility PFS payment rates for individual services. In the case of new medical devices for which high growth in volume of a service as it diffuses into clinical practice may lead to a decrease in the cost of expensive items, outdated price inputs can result in significant overestimation of resource costs.

Such inaccurate resource input costs may distort the nonfacility PE RVUs used to calculate PFS payment rates for individual services. As we have previously noted, OPPS payment rates are based on auditable hospital data and are updated annually. Given the differences in the validity of the data used to calculate payments under the PFS and OPPS, we believe that the nonfacility PFS payment rates for procedures that exceed those for the same procedure when in a facility result from inadequate or inaccurate direct PE inputs, especially in price or time assumptions, as compared to the more accurate OPPS data. On these bases, we are proposing a change in the PE methodology beginning in CY 2014 and subsequent years. To improve the accuracy of PFS nonfacility payment rates for each calendar year, we are proposing to use the current year OPPS or ASC rates as a point of comparison in establishing PE RVUs for services under the PFS. In setting PFS rates, we would compare the PFS payment rate for a service furnished in an office setting to the total Medicare payment to practitioners and facilities for the same service when furnished in a hospital outpatient setting. For services on the ASC list, we would make the same comparison except we would use the ASC rate as the point of comparison instead of the OPPS rate.

We are proposing to limit the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined amount Medicare would pay for the same code in the facility setting. That is, if the nonfacility PE RVUs for a code would result in a higher payment than the corresponding

OPPS or ASC payment rate and PFS facility PE RVUs (when applicable) for the same code, we would reduce the nonfacility PE RVU rate so that the total nonfacility payment does not exceed the total Medicare payment made for the service in the facility setting. To maintain the greatest consistency and transparency possible, we are proposing to use the current year PFS conversion factor, as reflected in Figure B1. Similarly, we are proposing to use current year OPPS or ASC rates in the comparison.

Figure B1



For services with no work RVUs, we are proposing to compare the total nonfacility PFS payment to the OPPS payment rates directly since no PFS payment is made for these services when furnished in the facility setting.

We are proposing to exempt the following services from this policy:

Services Without Separate OPPS Payment rates: We are proposing to exclude services without separately payable OPPS rates from this methodical change since there would be no OPPS rate to which we could compare the PFS nonfacility PE RVUs. We note that there would also be no ASC rate for these services since ASCs are only approved to furnish a subset of OPPS services.

Codes Subject to the DRA Imaging Cap: We are proposing to exclude services capped at the OPPS payment rate by the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) from this policy. The DRA provision limits PFS payment for most imaging procedures to the amount paid under the OPPS system. This policy applies to the technical component of imaging services, including X-ray, ultrasound, nuclear medicine, MRI, CT, and fluoroscopy services. Screening and diagnostic mammograms are exempt. Since payment for these procedures is capped by statute we are excluding them from this policy.

Codes with Low Volume in the OPPS or ASC: We are proposing to exclude any service for which 5% percent or less of the total number of services are furnished in the OPPS setting relative to the total number of PFS/OPPS allowed services.

Codes with ASC Rates Based on PFS Payment Rates: To avoid issues of circularity, we are proposing to exclude ASC services subject to the ''office-based'' procedure payment policies for which payment rates are based on the PFS nonfacility PE RVUs. We direct interested readers to the CY 2013 OPPS final rule (77 FR 68444) for additional information regarding this payment policy.

Codes Paid in the Facility at Nonfacility PFS Rates: To avoid issues of circularity, we are also proposing to exclude services that are paid in the facility setting at nonfacility payment rates. This would include certain professional-only services where the resource costs for practitioners are assumed to be similar in both settings.

Codes with PE RVUs Developed Outside the PE Methodology: We are also proposing to exclude services with PE RVUs established outside the PE Methodology through notice and comment rulemaking.

Addendum B of this proposed rule with comment period displays the PE RVUs that would result from implementation of this proposed change in the PE methodology.

In discussing resource input issues, some stakeholders have previously suggested that the direct costs (for example, clinical labor, disposable supplies and medical equipment) involved in furnishing a service are similar in both the nonfacility and facility settings. Others have suggested that facilities, like hospitals, have greater purchasing power for medical equipment and disposable supplies so that the direct costs for a facility to furnish a service can be lower than costs for a physician practice furnishing the same service. This proposed policy does not assume that the direct costs to furnish a service in the nonfacility setting are always lower than in the facility setting. Medicare payment methodologies, including both OPPS and the PFS PE methodology, incorporate both direct and indirect costs (administrative labor, office expenses, and all other expenses). This proposed policy is premised on the idea that there are significantly greater indirect resource costs that are carried by facilities even in the event that the direct costs involved in furnishing a service in the office and facility settings are comparable.

We believe this proposal provides a reliable means for Medicare to set upper payment limits for office-based procedures based on relatively more

reliable cost information available for the same procedures when furnished in a facility setting where the cost structure would be expected to be somewhat, if not significantly, higher than the office setting. We believe that the current basis for estimating the resource costs involved in furnishing a PFS service is significantly encumbered by our current inability to obtain accurate information regarding supply and equipment prices, as well as procedure time assumptions. We believe that this policy will mitigate the negative impact of these difficulties on both the appropriate relativity of PFS services and overall Medicare spending. A wide range of stakeholders and public commenters have pointed to the nonfacility setting as the most cost-effective location for services. Given the significantly higher cost structure of facilities (as discussed above) we believe that this presumption is accurate. In its March 2012 report to Congress, MedPAC recommended that Medicare should seek to pay similar amounts for similar services across payment settings, taking into account differences in the definitions of services and patient severity. (MedPAC March 2012 Report to Congress, page 46) We believe that the proposed change to our PFS PE methodology will more appropriately reflect resource costs in the nonfacility setting.

b. Ultrasound Equipment Recommendations

In the CY 2012 PFS proposed rule (76 FR 42796), we asked the AMA RUC to review the ultrasound equipment described in the direct PE input database. We specifically asked for review of the ultrasound equipment items described in the direct PE input database and whether the ultrasound equipment listed for specific procedure codes is clinically necessary.

In response, the AMA RUC recommended creating several new equipment inputs in addition to the revision of current equipment inputs for ultrasound services. The AMA RUC also forwarded pricing information for new and existing equipment items from certain medical specialty societies that represent the practitioners who furnish these services. In the following paragraphs, we summarize the AMA RUC recommendations, address our review of the provided information, and describe proposed changes to the direct PE inputs used in developing PE RVUs for these services.

(1) Equipment Rooms

The AMA RUC made a series of recommendations regarding the ultrasound equipment items included in direct PE input equipment packages called ''rooms.'' Specifically, the AMA RUC recommended adding several new equipment items to the equipment packages called ''room, ultrasound, general'' (EL015) and ''room, ultrasound, vascular'' (EL016). The AMA RUC also recommended creating a similar direct PE input equipment package called ''room, ultrasound, cardiovascular.'' In considering these recommendations, we identified a series of new concerns regarding the makeup of these equipment packages and because there are several different ways to handle these concerns, we are seeking public comment from additional stakeholders prior to proposing to implement any of these recommended changes through future rulemaking.

We note that the existing ''rooms'' for ultrasound technology include a greater number of individual items than the ''rooms'' for other kinds of procedures. For example, the equipment package for the ''room, basic radiology'' (EL012) contains only two items: An x-ray machine and a camera. Ordinarily under the PFS, direct PE input packages for ''rooms'' include only equipment items that are typically used in furnishing every service in that room. When equipment items beyond those included in a ''room'' are typically used in furnishing a particular procedure, the additional equipment items for that procedure are separately reflected in the direct PE input database in addition to the ''room'' rather than being included in the room. When handled in this way, the room includes only those inputs that are common to all services furnished in that room type, and thus the direct PE inputs are appropriate for the typical case of each particular service. When additional equipment items are involved in furnishing a particular service, they are included as an individual PE input only for that particular service.

In contrast, the equipment items currently included in the ''room, ultrasound, general'' are: the ultrasound system, five different transducers, two probe starter kits, two printers, a table, and various other items. We do not believe that it is likely that all of these items would be typically used in furnishing each service. For example, we do not believe that the typical ultrasound study would require the use of five different ultrasound transducers. However, the costs of all of these items are incorporated into the resource inputs for every service for which the ultrasound room is a direct PE input, regardless of whether each of those items is typically used in furnishing the particular service. This increases the resource cost for every service that uses the room regardless of whether or not each of the individual items is typically used in furnishing a particular procedure.

Instead of incorporating the AMA RUC's recommendation to add more equipment items to these ultrasound equipment ''room'' packages, we believe that we should continue to consider the appropriateness of the full number of items in the ultrasound ''rooms'' in the context of maintaining appropriate relativity with other services across the PFS. We seek comment from stakeholders, including the AMA RUC, on the items included in the ultrasound rooms, especially as compared to the items included in other equipment ''rooms.'' We believe that it would be appropriate to consider these comments in future rulemaking. Specifically we seek comment on whether equipment packages called ''rooms'' should include all of the items that might be included in an actual room, just the items typically used for every service in such a room, or all of the items typically used in typical services furnished in the room. We believe that it would be most appropriate to propose changes to the ''room, ultrasound, general'' (EL015) and ''room, ultrasound, vascular'' (EL016) in the context of considering comments on this broader issue. We also believe that consideration of the broader issue will help determine whether it would be appropriate to create a ''room, ultrasound, cardiovascular,'' and if so, what items would be included in this equipment package.

In addition to the concerns regarding the contents of the ultrasound ''room'' packages, we are also concerned about the pricing information submitted through the AMA RUC to support its recommendation to add equipment to the ultrasound room packages. The highest-price item used in pricing the existing equipment input called ''room, ultrasound, general'' (EL015), is a ''GE Logic 9 ultrasound system,'' currently priced at $220,000. As part of a current AMA RUC recommendation, a medical specialty society recommended increasing the price of that item to $314,500. However, that recommendation did not include documentation to support the pricing level, such as a copy of a paid invoice for the equipment. Furthermore, the recommended price conflicts with certain publicly available information. For example, the *Milwaukee Sentinel-Journal* reported in a February 9, 2013 article that the price for GE ultrasound equipment ranges from ''$7,900 for a hand-held ultrasound to $200,000 for its

most advanced model.'' The same article points to an item called the ''Logiq E9'' as the ultrasound machine most used by radiologists and priced from $150,000 to $200,000. *http://www.jsonline.com/business/ge-sees-strong-future-with-its-ultrasound-business-uj8mn79-190533061.html*

At this time, are unsure how to best reconcile the information disclosed by the manufacturer to the press and the prices submitted by the medical specialty society for use in updating the direct PE input prices. We believe discrepancies, such as these, exemplify the potential problem with updating prices for particular items based solely on price quotes or information other than copies of paid invoices. However, copies of paid invoices must also be evaluated carefully. The information presented in the article regarding the price for hand-held ultrasound devices raises questions about the adequacy of paid invoices, too, in determining appropriate input costs. The direct PE input described in the database as ''ultrasound unit, portable'' (EQ250) is currently priced at $29,999 based on a submitted invoice, while the article cites that GE sells a portable unit for as low as $7,900. We are seeking comment on the appropriate price to use as the typical cost for portable ultrasound units.

Additionally, we are not proposing to revise the equipment items, or to change the prices of items, included in these rooms. Instead, pending our receipt and consideration of additional information, the proposed direct PE input database continues to include the current prices for the ''room, ultrasound, general'' (EL015), ''room, ultrasound, vascular'' (EL016), and ''ultrasound unit, portable'' (EQ250).

(2) New Equipment Inputs and Price Updates

Ultrasound Unit, portable, breast procedures. The AMA RUC recommended that a new direct PE input, ''ultrasound unit, portable, breast procedures,'' be created for breast procedures that are performed in a surgeon's office and where ultrasound imaging is included in the code descriptor. These services are described by CPT codes 19105 (Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma), 19296 (Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy), and 19298 (Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance). We are creating this input. The pricing information submitted for this item is a paid invoice and two price quotes. As we have previously stated, we believe that copies of paid invoices are more likely to reflect actual resource costs associated with equipment and supply items than quotes or other information. Therefore, we are proposing a price of $33,930, which reflects the price displayed on the submitted copy of the paid invoice. We are not using the quotes as we do not believe that quotes provide reliable information about the prices that are actually paid for medical equipment.

Endoscopic Ultrasound Processor. The AMA RUC recommended creating a new direct PE input called ''endoscopic ultrasound processor,'' for use in furnishing the service described by CPT code 31620 (Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])). We are creating this equipment item to use as an input in the proposed direct PE input database. The price associated with the ''endoscopic ultrasound processor'' will be $59,925, which reflects the price documented on the copy of the paid invoice submitted with the recommendation.

Bronchofibervideoscope. The AMA RUC recommended creating a new direct PE input called ''Bronchofibervideoscope,'' for use in furnishing the service described by CPT code 31620 (Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])). We are creating this new equipment item to use as an input in the proposed direct PE input database. However, this item has no price associated with it in the proposed direct PE input database because we did not receive any information that would allow us to price the item accurately. Consequently, we seek copies of paid invoices for this equipment item so that we can price the item accurately in the future.

Endoscope, ultrasound probe, drive (ES015). The AMA RUC forwarded pricing information to us regarding the existing input called ''endoscope, ultrasound probe, drive'' (ES015). This information included a copy of a paid invoice. Based on this information, we are proposing to change the price associated with ES015 to $13,256.25, which reflects the price documented on the submitted copy of the paid invoice.

(3) Ultrasound Equipment Input Recommendations for Particular Services

The AMA RUC made recommendations regarding the typical ultrasound items used in furnishing particular services. In general, the AMA RUC recommended that the existing equipment items accurately described the typical equipment used in furnishing particular services. However, for some CPT codes the AMA RUC recommended changing the associated equipment inputs that appear in the direct PE input database. Based on our review of these recommendations, we have generally agreed with the AMA RUC regarding these recommended changes, and these changes are reflected in the proposed direct PE input database. Table 10 displays the codes with proposed changes to ultrasound equipment. However, for certain codes we do not agree with the recommendations of the AMA RUC. The following paragraphs address the changes we are proposing that differ from the recommendations of the AMA RUC.

For a series of cardiovascular services that include ultrasound technology, the AMA RUC recommended removing certain equipment items and replacing those items with a new item called ''room, ultrasound, cardiovascular.'' As we described in the preceding paragraphs, we are not proposing to create the ''room, ultrasound, cardiovascular'' and therefore will not propose to add this ''room'' an input for these services. However, we note that the newly recommended equipment package incorporates many of the same kinds of items as the currently existing ''room, ultrasound, vascular'' (EL016). We agree with the AMA RUC's suggestion that the existing equipment inputs for the relevant services listed in Table 10 do not reflect typical resource costs of furnishing the services. We believe that, pending our further consideration of the ultrasound ''room'' equipment packages, it would be appropriate to use the existing ''room, ultrasound, vascular'' (EL016) as a proxy for resource costs for these services. Therefore, the proposed direct PE input database reflects this proposed change.

In the case of CPT code 76942 (Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation), we agree with the AMA RUC's

recommendation to replace the current equipment input of the ''room, ultrasound, general'' (EL015) with ''ultrasound unit, portable'' (EQ250). We note that this service is typically reported with other codes that describe the needle placement procedures and that the recommended change in equipment from a room to a portable device reflects a change in the typical kinds of procedures reported with this image guidance service. Given this change, we believe that it is appropriate to reconsider the procedure time assumption currently used in establishing the direct PE inputs for this code is 45 minutes, which we believe is inaccurate. We reviewed the services reported with CPT code 76942 to identify the most common procedures furnished with this image guidance. The code most frequently reported with CPT code 76942 is CPT 20610 (Arthrocentesis, aspiration and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa). The assumed procedure time for this service is five minutes. The vast majority of other procedures frequently reported with CPT code 76942 range in procedure time assumptions from 5 to 20 minutes. Therefore, in addition to proposing the recommended change in equipment inputs associated with the code, we are also proposing to change the procedure time assumption used in establishing direct PE inputs for the service from 45 to 10 minutes, based on our analysis of thirty needle placement procedures most frequently reported with CPT code 76942. We note that this will reduce the clinical labor and equipment minutes associated with the code from 58 to 23 minutes. This change is reflected in the proposed direct PE input database. We also note that this code has been proposed as a potentially misvalued code in section II.B.3.b.1.

TABLE 10—CODES WITH PROPOSED CHANGES TO ULTRASOUND EQUIPMENT FOR CY 2014

CPT code	Descriptor	CY 2013 CMS Equipment code	CY 2013 Equipment description	Proposed CY 2014 Equipment CMS code	Proposed CY 2014 Equipment description
19105	Cryosurg ablate fa each	EQ250	ultrasound unit, portable	NEW	ultrasound unit, portable, breast procedures.
19296	Place po breast cath for rad	EL015	room, ultrasound, general	NEW	ultrasound unit, portable, breast procedures.
19298	Place breast rad tube/caths	EL015	room, ultrasound, general	NEW	ultrasound unit, portable, breast procedures.
31620	Endobronchial us add-on	n/a		NEW	Bronchofibervideoscope.
		n/a		NEW	Endoscopic ultrasound processor.
52649	Prostate laser enucleation	EQ255	ultrasound, noninvasive bladder scanner w-cart.	EQ250	ultrasound unit, portable.
76376	3d render w/o postprocess	EL015	room, ultrasound, general	Remove input.	
76775	Us exam abdo back wall lim	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable.
76820	Umbilical artery echo	EQ249	ultrasound color doppler, transducers and vaginal probe.	EL015	room, ultrasound, general.
76857	Us exam pelvic limited	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable.
76870	Us exam scrotum	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable.
76872	Us transrectal	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable.
76942	Echo guide for biopsy	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable.
93303	Echo guide for biopsy	EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).	EL016	room, ultrasound, vascular.
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
		EQ252	ultrasound, echocardiography analyzer software (ProSolv).		
93304	Echo transthoracic	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93306	Tte w/doppler complete	EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).	EL016	room, ultrasound, vascular.
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
		EQ252	ultrasound, echocardiography analyzer software (ProSolv).		
93307	Tte w/o doppler complete	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		

TABLE 10—CODES WITH PROPOSED CHANGES TO ULTRASOUND EQUIPMENT FOR CY 2014—Continued

CPT code	Descriptor	CY 2013 CMS Equipment code	CY 2013 Equipment description	Proposed CY 2014 Equipment CMS code	Proposed CY 2014 Equipment description
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93308	Tte f-up or lmtd	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93312	Echo transesophageal	EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).	EL016	room, ultrasound, vascular.
		EQ252	ultrasound, echocardiography analyzer software (ProSolv).		
		EQ256	ultrasound, transducer (TEE Omniplane II).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93314	Echo transesophageal	EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).	EL016	room, ultrasound, vascular.
		EQ256	ultrasound, transducer (TEE Omniplane II).		
		EQ252	ultrasound, echocardiography analyzer software (ProSolv).		
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
93320	Doppler echo exam heart	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93321	Doppler echo exam heart	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93325	Doppler color flow add-on	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93350	Stress tte only	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93351	Stress tte complete	EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).	EL016	room, ultrasound, vascular.
93980	Penile vascular study	EL015	room, ultrasound, general	EQ249	ultrasound color doppler, transducers and vaginal probe.
93981	Penile vascular study	EL015	room, ultrasound, general	EQ249	ultrasound color doppler, transducers and vaginal probe.

4. Collecting Data on Services Furnished in Off-Campus Hospital Provider-Based Departments

In recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the furnishing of physicians' services in a hospital outpatient setting (for example, see Ostrom, Carol M. ''Why you might pay twice for one visit to a doctor,'' *Seattle Times.* November 3, 2012, and O'Malley, Ann, Amelia M. Bond, and Robert Berenson. *Rising hospital employment of physicians: better quality, higher costs?* Issue Brief No. 136, Center for Studying Health System Change. August 2011). When a Medicare

beneficiary receives outpatient services in a hospital, Medicare generally pays more in total than when the beneficiary receives those same services in a freestanding clinic or physician office. As more physician practices become hospital-based, news articles have highlighted beneficiary liability for the additional coinsurance for the ''facility fee,'' which is the payment in addition to the physician payment when services are furnished in a hospital. MedPAC has questioned the appropriateness of increased Medicare payment and beneficiary cost-sharing when physician offices become hospital outpatient departments, and has recommended that Medicare pay selected hospital outpatient services at physician fee schedule rates (MedPAC March 2012 *Report to Congress*).

The total l payment (including both Medicare program payment and beneficiary cost-sharing) generally is higher when outpatient services are furnished in the hospital outpatient setting rather than a physician office. Both the PFS and the hospital outpatient prospective payment system (OPPS) establish payment based on the relative resources involved in furnishing a service. As described in section II.B.1.b. of this proposed rule, the relative values for services furnished in the physician office setting under the PFS reflect not only payment for the practitioner's work, but also the direct expenses (clinical labor, medical equipment, and medical supplies) and the indirect expenses (administrative labor, office expense, and all other expenses) typically involved in furnishing the service. Under section 1833(t) of the Act, Medicare provides separate payment through the OPPS to hospitals for certain items and services furnished to registered hospital outpatients that are based on the relativity of the resource costs (labor and capital) involved in furnishing those hospital services. In general, we expect hospitals to have higher overall resource requirements than physician offices because hospitals are required to meet conditions of participation, to maintain standby capacity for emergency situations, and to be available to address a wide variety of complex medical needs in a community. When services are furnished in the hospital setting, such as in off-campus provider based departments, Medicare pays the physician under the PFS at a typically lower facility payment rate but then also pays the hospital under the OPPS for the facility resources required to furnish the service. The beneficiary pays coinsurance for both the physician PFS payment and the hospital OPPS payment. The term ''facility fee'' refers to this additional hospital outpatient payment.

Upon acquisition of a physician practice, hospitals frequently treat the practice locations as off-campus provider-based departments of the hospital and bill Medicare for services furnished at those locations under the OPPS (for further information on the provider-based regulations at § 413.65, see *http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2-sec413-65.pdf*). Since October 1, 2002, we have not required hospitals to seek from CMS a determination of provider-based status for a facility that is located off campus. We also do not have a formal process for gathering information on the frequency, type, and payment for services furnished in off-campus provider-based departments of the hospital.

To better understand the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments, we are considering collecting information that would allow us to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments. We have considered several potential methods. Claims-based approaches could include (1) creating a new place of service code for off-campus departments of a provider under 42 CFR 413.65(g)(2) as part of item 24B of the CMS–1500 claim form, comparable to current place of service codes such as ''22 Outpatient'' and ''23 Emergency Room-Hospital'' when physician services are furnished in an off-campus provider-based department, or (2) creating a HCPCS modifier that could be reported with every code for services furnished in an off-campus provider-based department of a hospital on the CMS–1500 claim form for physician services and the UB–04 (CMS form 1450) for hospital outpatient claims. In addition, we also have considered asking hospitals to break out the costs and charges for their provider-based departments as outpatient service cost centers on the Medicare hospital cost report, form 2552–10. We note that some hospitals already break out these costs voluntarily or because of cost reporting requirements for the 340B Drug Discount program but this practice is not consistent or standardized. We welcome public comment on the best means for collecting information on the frequency, type, and payment for services furnished in off-campus provider-based departments of hospitals.

B. Misvalued Codes

1. Valuing Services Under the PFS

Section 1848(c) of the Act requires the Secretary to determine relative values for physicians' services based on three components: work; PE; and malpractice. Section 1848(c)(1)(A) of the Act defines the work component to include ''the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service.'' In addition, section 1848(c)(2)(C)(i) of the Act specifies that ''the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and intensity required in furnishing the service.'' Section 1848(c)(1)(B) of the Act defines the PE component as ''the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.'' (See section I.A.2. for more detail on the PE component.) Section 1848(c)(1)(C) of the Act defines the malpractice component as ''the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service.'' Sections 1848 (c)(2)(C)(ii) and (iii) of the Act specify that PE and malpractice expense RVUs shall be determined based on the relative PE/malpractice expense resources involved in furnishing the service.

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 3134(a) of the Affordable Care Act added a new section 1848(c)(2)(K) to the Act, which requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 3134(a) of the Affordable Care Act also added a new section 1848(c)(2)(L) to the Act which, requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, identified using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.A.1. of this proposed rule, each year we develop and propose appropriate adjustments to the RVUs, taking into account the recommendations provided by the

American Medical Association/Specialty Society Relative Value Scale Update Committee (AMA RUC), the Medicare Payment Advisory Commission (MedPAC), and others. For many years, the AMA RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by the law. We may also consider analyses of physician time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS) National Database, and the Physician Quality Reporting Initiative (PQRI) databases. In addition to considering the most recently available data, we also assess the results of physician surveys and specialty recommendations submitted to us by the AMA RUC. We conduct a clinical review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available in addition to taking into account the results of consultations with organizations representing physicians. In accordance with section 1848(c) of the Act, we determine appropriate adjustments to the RVUs, explain the basis of these adjustments, and respond to public comments in the PFS proposed and final rules.

2. Identifying, Reviewing, and Validating the RVUs of Potentially Misvalued Services

a. Background

In its March 2006 Report to the Congress, MedPAC noted that ''misvalued services can distort the price signals for physicians' services as well as for other health care services that physicians order, such as hospital services.'' In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''when a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PEs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PEs rise. In the ensuing years since MedPAC's 2006 report, additional groups of potentially misvalued services have been identified by the Congress, CMS, MedPAC, the AMA RUC, and other stakeholders.

In recent years, CMS and the AMA RUC have taken increasingly significant steps to identify and address potentially misvalued codes. As MedPAC noted in its March 2009 Report to Congress, in the intervening years since MedPAC made the initial recommendations, ''CMS and the AMA RUC have taken several steps to improve the review process.'' Most recently, section 1848(c)(2)(K)(ii) of the Act (as added by section 3134(a) of the Affordable Care Act) directed the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following seven categories:

- Codes and families of codes for which there has been the fastest growth;
- Codes and families of codes that have experienced substantial changes in PEs;
- Codes that are recently established for new technologies or services;
- Multiple codes that are frequently billed in conjunction with furnishing a single service;
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment;
- Codes which have not been subject to review since the implementation of the RBRVS (the so-called 'Harvard-valued codes'); and
- Other codes determined to be appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Finally, section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the physician fee schedule.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes in all seven of the categories specified in section 1848(c)(2)(K)(ii) of the Act, and we plan to continue our work examining potentially misvalued codes in these areas over the upcoming years. In the current process, we identify potentially misvalued codes for review, and request recommendations from the AMA RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The AMA RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed more than 1,000 potentially misvalued codes to refine work RVUs and direct PE inputs. We have adopted appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the CY 2012 PFS proposed rule, we proposed to identify and review potentially misvalued codes in the category of ''Other codes determined to be appropriate by the Secretary,'' referring to a list of the highest PFS expenditure services, by specialty, that had not been recently reviewed (76 FR 73059 through 73068).

In the CY 2012 final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time

(76 FR 73055 through 73958), and established a process for the annual public nomination of potentially misvalued services.

One of the priority categories for review of potentially misvalued codes is services that have not been subject to review since the implementation of the PFS (the so-called ''Harvard-valued codes''). In the CY 2009 PFS proposed rule, we requested that the AMA RUC engage in an ongoing effort to review the remaining Harvard-valued codes, focusing first on the high-volume, low intensity codes (73 FR 38589). For the Fourth Five-Year Review (76 FR 32410), we requested that the AMA RUC review services that have not been reviewed since the original implementation of the PFS with annual utilization greater than 30,000 (Harvard-valued—Utilization > 30,000). In the CY 2013 final rule with comment period, we identify for review the potentially misvalued codes for Harvard-valued services with annual allowed charges that total at least $10,000,000 (Harvard-valued—Allowed charges ≥$10,000,000).

In addition to the Harvard-valued codes, in the same rule we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed physician time and codes with no physician work and have listed physician time).

c. Validating RVUs of Potentially Misvalued Codes

In addition to identifying and reviewing potentially misvalued codes, section 3134(a) of the Affordable Care Act added section 1848(c)(2)(L) of the Act, which specifies that the Secretary shall establish a formal process to validate RVUs under the PFS. The validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. The Secretary is directed, as part of the validation, to validate a sampling of the work RVUs of codes identified through any of the seven categories of potentially misvalued codes specified by section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services.

In the CY 2011 PFS proposed rule (75 FR 40068) and CY 2012 PFS proposed rule (76 FR 42790), we solicited public comments on possible approaches, methodologies, and data sources that we should consider for a validation process. A summary of the comments along with our responses are included in the CY 2011 PFS final rule with comment period (75 FR 73217) and the CY 2012 PFS final rule with comment period (73054 through 73055).

We have entered into two contracts with outside entities to develop validation models for RVUs. During a 2-year project, the RAND Corporation will use available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity. The model design will be informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and AMA RUC processes. RAND will use a representative set of CMS-provided codes to test the model. RAND will consult with a technical expert panel on model design issues and the test results.

The second contract is with the Urban Institute. Given the central role of time in establishing work RVUs and the concerns that have been raised about the current time values, a key focus of the project is collecting data from several practices for services selected by the contractor. The data will be used to develop time estimates. Urban Institute will use a variety of approaches to develop objective time estimates, depending on the type of service, which will be a very resource-intensive part of the project. Objective time estimates will be compared to the current time values used in the fee schedule. The project team will then convene groups of physicians from a range of specialties to review the new time data and their potential implications for work and the ratio of work to time.

3. CY 2014 Identification and Review of Potentially Misvalued Services

a. Public Nomination of Potentially Misvalued Codes

In the CY 2012 PFS final rule with comment period, we finalized a process for the public to nominate potentially misvalued codes (76 FR 73058). The public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation during the 60-day public comment period following the release of the annual PFS final rule with comment period. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in the peer reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following: technique; knowledge and technology; patient population; site-of-service; length of hospital stay; and physician time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work, that is, diffusion of technology.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of physician time, work RVU, or direct PE inputs using other data sources (for example, Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS) National Database, and the Physician Quality Reporting System (PQRS) databases).
- National surveys of physician time and intensity from professional and management societies and organizations, such as hospital associations.

After we receive the nominated codes during the 60-day comment period following the release of the annual PFS final rule with comment period, we evaluate the supporting documentation and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate whether we are proposing each nominated code as a potentially misvalued code.

We did not receive publicly nominated potentially misvalued codes for inclusion in this proposed rule. We look forward to receiving new code nominations for inclusion in the CY 2015 proposed rule to continue with our efforts to identify potentially misvalued codes.

b. Potentially Misvalued Codes

(1) Contractor Medical Director Identified Potentially Misvalued Codes

After publishing the CY final rule with comment period, we began considering additional ways to broaden participation in the process of identifying potentially misvalued codes. We solicited the input of Medicare contractor medical directors (CMDs) in developing a list of potentially misvalued codes. CMDs offer a unique perspective on the Medicare program. Medicare Administrative Contractors administer the Medicare program in their assigned geographic area and each has at least one CMD that serves as its director. As a group, CMDs represent a variety of medical specialties, which makes them a diverse group of physicians capable of providing opinions across the vast scope of services covered under the PFS. In addition to being physicians, they are on the front line of administering the Medicare program; and their offices often serve as the first point of contact for any provider with questions regarding coverage, coding and claims processing. CMDs spend a significant amount of time communicating directly with providers and the health care industry discussing more than just the broad aspects of the Medicare program but also engaging in and facilitating specific discussions around individual services. Through their development of evidence-based local coverage determinations (LCDs), CMDs also have experience developing policy based on research. In consultation with our CMDs, we have identified the following list of codes that we are proposing as potentially misvalued. We include a brief discussion of the reasons for proposing these codes as potentially misvalued.

TABLE 11—CODES IDENTIFIED IN CONSULTATION WITH CMDS AS POTENTIALLY MISVALUED

CPT code	Short descriptor
17311	Mohs 1 stage h/n/hf/g.
17313	Mohs 1 stage t/a/l.
21800	Treatment of rib fracture.
22035	Closed tx spine process fx.
27193	Treat pelvic ring fracture.
33960	External circulation assist.
33961	External circulation assist, each subsequent day.
47560	Laparoscopy w/cholangio.
47562	Laparoscopic cholecystectomy.
47563	Laparo cholecystectomy/graph.
55845	Extensive prostate surgery.
55866	Laparo radical prostatectomy.
64566	Neuroeltrd stim post tibial.
76942	Echo guide for biopsy.

CPT codes 17311 (Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation, head, neck, hands, feet genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks) and 17313 (Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histpathologic preparation including routine stains(s) of the trunk, arms, or legs; first stage, up to 5 tissue blocks) are proposed as potentially misvalued codes because based on CMD comments, we believe that the code may be overvalued.

CPT codes 21800 (Closed treatment of rib fracture, uncomplicated, each), 22305 (Closed treatment of vertebral process fracture(s)) and 27193 (Closed treatment of pelvic ring fracture, dislocation, diastasis or subluxation, without manipulation) is proposed for review. We are considering the appropriateness of having a 90-day global surgical package for a procedure that is performed in settings other than the inpatient setting 33 percent of the time. We believe it is unlikely that it is appropriate for a procedure performed outside of the inpatient hospital setting at this frequency to have such a long global period. CPT codes 33960 (Prolonged extracorporeal circulation for cardiopulmonary insufficiency; initial day) and 33961 (Each subsequent day) are being proposed for review because CMDs were concerned about their current valuation of physician work. The CMD comment states that the service was originally valued when it was used primarily in premature neonates; but the service is now being furnished to adults with severe influenza, pneumonia and respiratory distress syndrome. We are concerned that, while the code currently includes 523 minutes of total physician time with 133 minutes of intraservice time, physicians are not typically furnishing the service over that entire time interval; rather, hospital-employed pump technicians are furnishing much of the work.

CPT codes 47560 (Laparoscopy, surgical; with guided transhepatic cholangiography, without biopsy), 47562 (Cholecystectomy) and 47563 (Cholecystectomy with cholangiography) we are proposing these codes as potentially misvalued because the more extensive code has lower work RVUs than the less extensive codes.

CPT codes 55845 (Prostatectomy, retropubic radical with or without nerve sparing with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes) and 55866 (Laparoscopy, surgical prostatectomy, retropubic radial, including nerve sparing, includes robotic assistance when performed) we are proposing as potentially misvalued because the RVUs for the laparoscopic procedure are higher than for the open procedure and, in general, a laparascopic procedure would not require greater resources than the open procedure.

We are proposing CPT 64566 (Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming) as a potentially misvalued code because we think that the procedure typically is furnished by support staff with supervision as opposed to being furnished by the physician. We are concerned that the current valuation is based on the procedure being furnished by a physician.

We are proposing CPT code 76942 (Ultrasonic guidance for needle placement (for example, biopsy, aspiration, injection, localization device), imaging supervision and interpretation) as a potentially misvalued code because of the high frequency with which it is billed with CPT code 20610 (Arthrocentesis aspiration and/or injection; major joint or bursa (for example, shoulder, hip, knee joint, subacromial bursa) in the CMD's geographic region. The CMD noted that some providers within the contractor's geographic area bill CPT code 76942 with every injection or aspiration of the knee. One CMD suggests that the payment for CPT code 76942 and CPT code 20610 should be combined to reduce the incentive for providers to always provide and bill separately for ultrasound guidance. We note that we are making a proposal regarding the direct PE inputs for CPT code 76942. Our claims data show that the procedure time assumption for CPT code 76942 is longer than the typical procedure with which the code is billed (for example, CPT code 20610). The proposed changes relating to CPT code 76942 are addressed in detail in section II.A.4.b.3. of this proposed rule. We believe that the discrepancy in procedure times and the resulting potentially inaccurate payment raises a fundamental concern regarding the incentive to furnish ultrasound guidance. However, we believe this

concern spans more than just an individual code for ultrasound guidance. Accordingly, we have proposed additional ultrasound guidance codes as potentially misvalued in Table 12. We are seeking public comment on including these codes as potentially misvalued codes. We are also seeking public comment on any similar codes that should be included on this list.

TABLE 12—CPT CODES FOR ULTRASOUND GUIDANCE

CPT code	Short descriptor
76930	Echo guide cardiocentesis.
76932	Echo guide for heart biopsy.
76936	Echo guide for artery repair.
76940	US guide tissue ablation.
76948	Echo guide ova aspiration.
76950	Echo guidance radiotherapy.
76965	Echo guidance radiotherapy.

(2) Improving the Valuation of the Global Surgical Package, Measuring Post-Operative Work

In the CY 2013 proposed rule, we sought comments on methods of obtaining accurate and current data on E/M services furnished as part of a global surgical package. Commenters provided a variety of suggestions including setting the all surgical services to a 0-day global period, requiring all E/M services to be separately billed, validating the global surgical packages with the hospital Diagnosis-Related Group length of stay data, and setting documentation standards for post-operative E/M services that could be audited. In addition to receiving the broader comments on measuring post-operative work, we also received a comment from the AMA RUC noting that the hospital and discharge day management services included in the global period for many surgical procedures may have been inadvertently removed from the time file in 2007. With its comment letter, the AMA RUC sent us a time file with updated post-operative visits for the services that arguably we incorrectly displayed with zero visits in the CMS time file. We said in the CY 2013 final rule with comment period that we would review this file and, if appropriate, propose modifications to the physician time file in the CY 2014 PFS proposed rule. We noted in the CY 2013 final rule with comment period that if time had been removed from the physician time file inadvertently, it would not have affected the physician work RVUs or direct PE inputs for these services. It would have a small impact on the indirect allocation of PE at the specialty level, which we would review when we explore this potential time file change.

After extensive review, we believe that the data were deleted from the time file due to an inadvertent error as noted by the AMA RUC. Thus, we are proposing to replace the missing post-operative hospital E/M visit information and time for the 117 codes that were identified by the AMA–RUC and displayed in Table 13. We believe this proposal would populate the physician time file with data that, absent the inadvertent error, would have been present in the time file.

TABLE 13—PROPOSED PHYSICIAN TIME CHANGES FOR CY 2014 POTENTIALLY MISVALUED CODES

CPT code	Short descriptor	AMA RUC-recommended visits				CY 2013 physician time	AMA RUC-recommended physician time
		99231	99232	99238	99291		
19368	Breast reconstruction	4	.....	1	.....	712	770
19369	Breast reconstruction	3	.....	1	.....	657	690
20100	Explore wound neck	2	.....	1	.....	218	266
20816	Replantation digit complete	5	.....	1	.....	671	697
20822	Replantation digit complete	3	.....	1	.....	587	590
20824	Replantation thumb complete	5	.....	1	.....	646	690
20827	Replantation thumb complete	4	.....	1	.....	610	625
20838	Replantation foot complete	8	.....	1	.....	887	986
20955	Fibula bone graft microvasc	6	.....	1	1	867	957
20969	Bone/skin graft microvasc	8	.....	1	.....	1,018	1,048
20970	Bone/skin graft iliac crest	8	.....	1	.....	958	988
20973	Bone/skin graft great toe	5	.....	1	.....	1,018	988
21139	Reduction of forehead	1	.....	1	.....	400	466
21151	Reconstruct midface lefort	2	.....	1	1	567	686
21154	Reconstruct midface lefort	3	.....	1	2	664	853
21155	Reconstruct midface lefort	2	.....	1	2	754	939
21175	Reconstruct orbit/forehead	.....	1	1	2	549	767
21182	Reconstruct cranial bone	.....	1	1	2	619	856
21188	Reconstruction of midface	1	.....	1	.....	512	572
22100	Remove part of neck vertebra	2	.....	1	.....	397	372
22101	Remove part thorax vertebra	3	.....	1	.....	392	387
22110	Remove part of neck vertebra	6	.....	1	.....	437	479
22112	Remove part thorax vertebra	7	.....	1	.....	507	530
22114	Remove part lumbar vertebra	7	.....	1	.....	517	530
22210	Revision of neck spine	7	.....	1	.....	585	609
22212	Revision of thorax spine	7	.....	1	.....	610	640
22214	Revision of lumbar spine	7	.....	1	.....	585	624
22220	Revision of neck spine	7	.....	1	.....	565	585
22222	Revision of thorax spine	8	.....	1	.....	630	651
22224	Revision of lumbar spine	8	.....	1	.....	620	666
22315	Treat spine fracture	1	.....	1	.....	257	252
22325	Treat spine fracture	6	.....	1	.....	504	528
22326	Treat neck spine fracture	6	.....	1	.....	452	480
22327	Treat thorax spine fracture	9	.....	1	.....	505	604
22548	Neck spine fusion	8	.....	1	1	532	673
22556	Thorax spine fusion	3	.....	1	1	525	557
22558	Lumbar spine fusion	2	.....	1	1	502	525

TABLE 13—PROPOSED PHYSICIAN TIME CHANGES FOR CY 2014 POTENTIALLY MISVALUED CODES—Continued

CPT code	Short descriptor	AMA RUC-recommended visits				CY 2013 physician time	AMA RUC-recommended physician time
		99231	99232	99238	99291		
22590	Spine & skull spinal fusion	3		1		532	501
22595	Neck spinal fusion	6		1		492	521
22600	Neck spine fusion	6		1		437	490
22610	Thorax spine fusion	8		1		468	549
22630	Lumbar spine fusion	3		1		501	487
22800	Fusion of spine	7		1		517	571
22802	Fusion of spine	4		1		552	538
22804	Fusion of spine	5		1		630	595
22808	Fusion of spine	5		1		553	530
22810	Fusion of spine	5		1		613	595
22812	Fusion of spine	8		1		666	700
31582	Revision of larynx	8		1		489	654
32650	Thoracoscopy w/pleurodesis	2		1		322	290
32656	Thoracoscopy w/pleurectomy	3		1		419	377
32658	Thoracoscopy w/sac fb remove	1		1		362	330
32659	Thoracoscopy w/sac drainage	2		1		414	357
32661	Thoracoscopy w/pericard exc	1		1		342	300
32664	Thoracoscopy w/th nrv exc	1		1		362	330
32820	Reconstruct injured chest	4		1	5	631	854
33236	Remove electrode/thoracotomy	4		1		258	346
33237	Remove electrode/thoracotomy	5		1		378	456
33238	Remove electrode/thoracotomy	5		1		379	472
33243	Remove eltrd/thoracotomy	5		1		504	537
33321	Repair major vessel	8		1		751	754
33332	Insert major vessel graft	8		1		601	604
33401	Valvuloplasty open	8		1		830	661
33403	Valvuloplasty w/cp bypass	8		1		890	638
33417	Repair of aortic valve	3		1	3	740	750
33472	Revision of pulmonary valve	1		1	5	665	780
33502	Coronary artery correction	3		1	3	710	688
33503	Coronary artery graft	6		1	3	890	838
33504	Coronary artery graft	5		1	3	740	789
33600	Closure of valve	6		1		800	628
33602	Closure of valve	6		1		770	628
33606	Anastomosis/artery-aorta	8		1		860	728
33608	Repair anomaly w/conduit	5		1		800	668
33690	Reinforce pulmonary artery	3		1	3	620	636
33702	Repair of heart defects	1		1	4	663	751
33722	Repair of heart defect	5		1		770	608
33732	Repair heart-vein defect	5		1		710	578
33735	Revision of heart chamber	3		1	4	740	770
33736	Revision of heart chamber	5		1		710	548
33750	Major vessel shunt	2		1	3	680	722
33764	Major vessel shunt & graft	2		1	4	710	750
33767	Major vessel shunt	5		1		800	608
33774	Repair great vessels defect	1		1	7	845	998
33788	Revision of pulmonary artery	3		1	3	770	736
33802	Repair vessel defect	3		1	2	558	556
33803	Repair vessel defect	3		1	2	618	586
33820	Revise major vessel	1		1	1	430	414
33824	Revise major vessel	1		1	3	588	615
33840	Remove aorta constriction	2		1	3	588	639
33845	Remove aorta constriction	1		1	3	710	726
33851	Remove aorta constriction	2		1	3	603	700
33852	Repair septal defect	2		1	3	663	719
33853	Repair septal defect	8		1		800	668
33917	Repair pulmonary artery	5		1		740	608
33920	Repair pulmonary atresia	6		1		800	658
33922	Transect pulmonary artery	5		1		618	546
33974	Remove intra-aortic balloon	1		1		406	314
34502	Reconstruct vena cava	6		1		793	741
35091	Repair defect of artery	11		1	2	597	790
35694	Arterial transposition	2		1		468	456
35901	Excision graft neck	4		1		484	482
35903	Excision graft extremity	3		1		408	416
47135	Transplantation of liver	23		1		1,501	1,345
47136	Transplantation of liver	28		1		1,301	1,329
49422	Remove tunneled ip cath	1		1		154	182
49429	Removal of shunt	6		1		249	317
50320	Remove kidney living donor	4		1		480	524

TABLE 13—PROPOSED PHYSICIAN TIME CHANGES FOR CY 2014 POTENTIALLY MISVALUED CODES—Continued

CPT code	Short descriptor	AMA RUC-recommended visits				CY 2013 physician time	AMA RUC-recommended physician time
		99231	99232	99238	99291		
50845	Appendico-vesicostomy	5	.....	1	.....	685	613
56632	Extensive vulva surgery	7	.....	1	.....	835	683
60520	Removal of thymus gland	2	.....	1	2	406	474
60521	Removal of thymus gland	5	.....	1	.....	457	445
60522	Removal of thymus gland	7	.....	1	.....	525	533
61557	Incise skull/sutures	3	.....	1	.....	529	510
63700	Repair of spinal herniation	3	.....	1	.....	399	401
63702	Repair of spinal herniation	3	.....	1	.....	469	463
63704	Repair of spinal herniation	8	.....	1	.....	534	609
63706	Repair of spinal herniation	8	.....	1	.....	602	679

(3) Codes With Higher Total Medicare Payments in Office Than in Hospital or ASC

We are proposing to address nearly 200 codes that we believe have misvalued resource inputs. These are codes for which the total PFS payment when furnished in an office or other nonfacility setting would exceed the total Medicare payment (the combined payment to the facility and the professional) when the service is furnished in a facility, either a hospital outpatient department or an ASC.

For services furnished in a facility setting we would generally expect the combined payment to the facility and the practitioner to exceed the PFS payment made to the professional when the service is furnished in the nonfacility setting. This payment differential is expected because it reflects the greater costs we would expect to be incurred by facilities relative to physicians furnishing services in offices and other non-facility settings. These greater costs are due to higher overhead resulting from differences in regulatory requirements and for facilities, such as hospitals, maintaining the capacity to furnish services 24 hours per day and 7 days per week. However, when we analyzed such payments, we identified nearly 300 codes that would result in greater Medicare payment in the nonfacility setting than in the facility setting. We believe these anomalous site-of-service payment differentials are the result of inaccurate resource input data used to establish rates under the PFS.

In this proposed rule, we are proposing to address these misvalued codes. Specifically, we are proposing to refine the PE methodology to limit the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined payment under the PFS and the OPPS (or the ASC payment system) when the service is furnished in the facility setting. We believe this is an efficient way to address these significant anomalies within the PE methodology and more appropriately value these services. We discuss this proposal in more detail in section II.A.4.b.3.

4. The Multiple Procedure Payment Reduction Policy

Medicare has long employed multiple procedure payment reduction (MPPR) policies to adjust payment to more appropriately reflect reduced resources involved with furnishing services that are frequently furnished together. Under these policies, we reduce payment for the second and subsequent services within the same MPPR category furnished in the same session or same day. These payment reductions reflect efficiencies that typically occur in either the PE or professional work or both when services are furnished together. With the exception of a few codes that are always reported with another code, the PFS values services independently to recognize relative resources involved when the service is the only one furnished in a session. Although some of our MPPR policies precede the Affordable Care Act, MPPRs can address the fourth category of potentially misvalued codes identified in section 1848(c)(2)(K) of the Act, as added by the Affordable Care Act, which is ''multiple codes that are frequently billed in conjunction with furnishing a single service'' (see 75 FR 73216). We are not proposing any new MPPRs in this proposed rule, but the following sections describe the history of MPPRs and the services currently covered by MPPRs.

a. Background

Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same beneficiary by a single physician, or physicians in the same group practice, on the same day, largely based on the presence of efficiencies in the PE and pre- and post-surgical physician work. Effective January 1, 1995, the MPPR policy, with this same percentage reduction, was extended to nuclear medicine diagnostic procedures (CPT codes 78306, 78320, 78802, 78803, 78806, and 78807). In the CY 1995 PFS final rule with comment period (59 FR 63410), we indicated that we would consider applying the policy to other diagnostic tests in the future.

Consistent with recommendations of MedPAC in its March 2005 Report to the Congress on Medicare Payment Policy, for CY 2006 PFS, we extended the MPPR policy to the TC of certain diagnostic imaging procedures furnished on contiguous areas of the body in a single session (70 FR 70261). This MPPR policy recognizes that for the second and subsequent imaging procedures furnished in the same session, there are some efficiencies in clinical labor, supplies, and equipment time. In particular, certain clinical labor activities and supplies are not duplicated for subsequent imaging services in the same session and, because equipment time and indirect costs are allocated based on clinical labor time, we also reduced those accordingly.

The imaging MPPR policy originally applied to computed tomography (CT) and computed tomographic angiography (CTA), magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA), and ultrasound services within 11 families of codes based on imaging modality and body region, and only applied to procedures furnished in a single session involving contiguous body areas within a family of codes. Additionally, this MPPR policy originally applied to TC-only services and to the TC of global services, but not to professional component (PC) services.

There have been several revisions to this policy since it was originally adopted. Under the current imaging

MPPR policy, full payment is made for the TC of the highest paid procedure, and payment for the TC is reduced by 50 percent for each additional procedure subject to this MPPR policy. We originally planned to phase in the imaging MPPR policy over a 2-year period, with a 25 percent reduction in CY 2006 and a 50 percent reduction in CY 2007 (70 FR 70263). However, section 5102(b) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted on December 20, 2006) amended the statute to place a cap on the PFS payment amount for most imaging procedures at the amount paid under the hospital outpatient prospective payment system (OPPS). In view of this new OPPS payment cap, we decided in the CY 2006 PFS final rule with comment period that it would be prudent to retain the imaging MPPR at 25 percent while we continued to examine the appropriate payment levels (71 FR 69659). The DRA also exempted reduced expenditures attributable to the imaging MPPR policy from the PFS budget neutrality provision. Effective July 1, 2010, section 1848(b)(4)(C) of the Act increased the MPPR on the TC of imaging services under the policy established in the CY 2006 PFS final rule with comment period from 25 to 50 percent. Section 1848(c)(2)(B)(v)(IV) of the Act exempted the reduced expenditures attributable to this further change from the PFS budget neutrality provision.

In the July 2009 U.S. Government Accountability Office (GAO) report entitled, *Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved when Services are Provided Together,* the GAO recommended that we take further steps to ensure that fees for services paid under the PFS reflect efficiencies that occur when services are furnished by the same physician to the same beneficiary on the same day. The GAO report recommended the following: (1) Expanding the existing imaging MPPR policy for certain services to the PC to reflect efficiencies in physician work for certain imaging services; and (2) expanding the MPPR to reflect PE efficiencies that occur when certain nonsurgical, nonimaging services are furnished together. The GAO report also encouraged us to focus on service pairs that have the most impact on Medicare spending.

In its March 2010 report, MedPAC noted its concerns about mispricing of services under the PFS. MedPAC indicated that it would explore whether expanding the unit of payment through packaging or bundling would improve payment accuracy and encourage more efficient use of services. In the CY 2009 and CY 2010 PFS proposed rules (73 FR 38586 and 74 FR 33554, respectively), we stated that we planned to analyze nonsurgical services commonly furnished together (for example, 60 to 75 percent of the time) to assess whether an expansion of the MPPR policy could be warranted. MedPAC encouraged us to consider duplicative physician work, as well as PE, in any expansion of the MPPR policy.

Section 1848(c)(2)(K) of the Act specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values. As a first step in applying this provision, in the CY 2010 final rule with comment period, we implemented a limited expansion of the imaging MPPR policy to additional combinations of imaging services.

Effective January 1, 2011, the imaging MPPR applies regardless of code family; that is, the policy applies to multiple imaging services furnished within the same family of codes or across families. This policy is consistent with the standard PFS MPPR policy for surgical procedures that does not group procedures by body region. The current imaging MPPR policy applies to CT and CTA, MRI and MRA, and ultrasound procedures furnished to the same beneficiary in the same session, regardless of the imaging modality, and is not limited to contiguous body areas.

As we noted in the CY 2011 PFS final rule with comment period (75 FR 73228), although section 1848(c)(2)(B)(v)(VI) of the Act specifies that reduced expenditures attributable to the increase in the imaging MPPR from 25 to 50 percent (effective for fee schedules established beginning with 2010 and for services furnished on or after July 1, 2010) are excluded from the PFS budget neutrality adjustment, it does not apply to reduced expenditures attributable to our policy change regarding additional code combinations across code families (noncontiguous body areas) that are subject to budget neutrality under the PFS. The complete list of codes subject to the CY 2011 MPPR policy for diagnostic imaging services is included in Addendum F.

As a further step in applying the provisions of section 1848(c)(2)(K) of the Act, on January 1, 2011, we implemented an MPPR for therapy services. The MPPR applies to separately payable ''always therapy'' services, that is, services that are only paid by Medicare when furnished under a therapy plan of care. As we explained in the CY 2011 PFS final rule with comment period (75 FR 73232), the therapy MPPR does not apply to contractor-priced codes, bundled codes, or add-on codes.

This MPPR for therapy services was first proposed in the CY 2011 proposed rule (75 FR 44075) as a 50 percent payment reduction to the PE component of the second and subsequent therapy services for multiple ''always therapy'' services furnished to a single beneficiary in a single day. It applies to services furnished by an individual or group practice or ''incident to'' a physician's service. However, in response to public comments, in the CY 2011 PFS final rule with comment period (75 FR 73232), we adopted a 25 percent payment reduction to the PE component of the second and subsequent therapy services for multiple ''always therapy'' services furnished to a single beneficiary in a single day.

Subsequent to publication of the CY 2011 PFS final rule with comment period, section 3 of the Physician Payment and Therapy Relief Act of 2010 (PPTRA) (Pub. L. 111–286) revised the payment reduction percentage from 25 percent to 20 percent for therapy services for which payment is made under a fee schedule under section 1848 of the Act (which are services furnished in office settings, or non-institutional services). The payment reduction percentage remained at 25 percent for therapy services furnished in institutional settings. Section 4 of the PPTRA exempted the reduced expenditures attributable to the therapy MPPR policy from the PFS budget neutrality provision. Section 633 of the ATRA revised the reduction to 50 percent of the PE component for all settings, effective April 1, 2013. Therefore, full payment is made for the service or unit with the highest PE and payment for the PE component for the second and subsequent procedures or additional units of the same service is reduced by 50 percent for both institutional and non-institutional services.

This MPPR policy applies to multiple units of the same therapy service, as well as to multiple different ''always therapy'' services, when furnished to the same beneficiary on the same day. The MPPR applies when multiple therapy services are billed on the same date of service for one beneficiary by the same practitioner or facility under the same National Provider Identifier (NPI), regardless of whether the services are furnished in one therapy discipline or multiple disciplines, including physical therapy, occupational therapy, or speech-language pathology.

The MPPR policy applies in all settings where outpatient therapy services are paid under Part B. This includes both services that are furnished in the office setting and paid under the PFS, as well as institutional services that are furnished by outpatient hospitals, home health agencies, comprehensive outpatient rehabilitation facilities (CORFs), and other entities that are paid for outpatient therapy services at rates based on the PFS.

In its June 2011 Report to Congress, MedPAC highlighted continued growth in ancillary services subject to the in-office ancillary services exception. The in-office ancillary exception to the general prohibition under section 1877 of the Act as amended by the Ethics in Patient Referrals Act, also known as the Stark law, allows physicians to refer Medicare beneficiaries for designated health services, including imaging, radiation therapy, home health care, durable medical equipment, clinical laboratory tests, and physical therapy, to entities with which they have a financial relationship under specific conditions. MedPAC recommended that we apply a MPPR to the PC of diagnostic imaging services furnished by the same practitioner in the same session as one means to curb excess self-referral for these services. The GAO already had made a similar recommendation in its July 2009 report.

In continuing to apply the provisions of section 1848(c)(2)(K) of the Act regarding potentially misvalued codes that result from ''multiple codes that are frequently billed in conjunction with furnishing a single service,'' in the CY 2012 final rule (76 FR 73071), we expanded the MPPR to the PC of Advanced Imaging Services (CT, MRI, and Ultrasound), that is, the same list of codes to which the MPPR on the TC of advanced imaging already applied. Thus, this MPPR policy now applies to the PC and the TC of certain diagnostic imaging codes. Specifically, we expanded the payment reduction currently applied to the TC to apply also to the PC of the second and subsequent advanced imaging services furnished by the same physician (or by two or more physicians in the same group practice) to the same beneficiary in the same session on the same day. However, in response to public comments, in the CY 2012 PFS final rule with comment period, we adopted a 25 percent payment reduction to the PC component of the second and subsequent imaging services.

Under this policy, full payment is made for the PC of the highest paid advanced imaging service, and payment is reduced by 25 percent for the PC for each additional advanced imaging service furnished to the same beneficiary in the same session. This policy was based on the expected efficiencies in furnishing multiple services in the same session due to duplication of physician work, primarily in the pre- and post-service periods, but with some efficiencies in the intraservice period.

This policy is consistent with the statutory requirement for the Secretary to identify, review, and adjust the relative values of potentially misvalued services under the PFS as specified by section 1848(c)(2)(K) of the Act. This policy is also consistent with our longstanding policies on surgical and nuclear medicine diagnostic procedures, under which we apply a 50 percent payment reduction to second and subsequent procedures. Furthermore, it was responsive to continued concerns about significant growth in imaging spending, and to MedPAC (March 2010 and June 2011) and GAO (July 2009) recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies.

In the CY 2013 final rule (77 FR 68933), we expanded the MPPR to the TC of certain cardiovascular and ophthalmology diagnostic tests. Although we proposed a 25 percent reduction for both diagnostic cardiovascular and ophthalmology services, we adopted a 20 percent reduction for ophthalmology services in the final rule with comment period (77 FR 68941) in response to public comments. For diagnostic cardiovascular services, full payment is made for the procedure with the highest TC payment, and payment is reduced by 25 percent for the TC for each additional procedure furnished to the same patient on the same day. For diagnostic ophthalmology services, full payment is made for the procedure with the highest TC payment, and payment is reduced by 20 percent for the TC for each additional procedure furnished to the same patient on the same day.

Although we are not proposing any new MPPR policies for CY 2014, we continue to look at expanding the MPPR based on efficiencies when multiple procedures are furnished together. Any specific proposals would be presented in future rulemaking and subject to further public comment.''

The complete list of services subject to the MPPRs on diagnostic imaging services, therapy services, diagnostic cardiovascular services and diagnostic ophthalmology services is shown in Addenda F through J.

C. Malpractice RVUs

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: Work, PE, and malpractice. From 1992 to 1999, malpractice RVUs were charge-based, using weighted specialty-specific malpractice expense percentages and 1991 average allowed charges. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 4505(f) of the BBA, which amended section 1848(c) of the Act, required us to implement resource-based malpractice RVUs for services furnished beginning in 2000. Therefore, initial implementation of resource-based malpractice RVUs occurred in 2000.

The statute also requires that we review and, if necessary, adjust RVUs no less often than every 5 years. The first review and update of resource-based malpractice RVUs was addressed in the CY 2005 PFS final rule with comment period (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). In the CY 2010 PFS final rule with comment period, we implemented the second review and update of malpractice RVUs. For a discussion of the second review and update of malpractice RVUs, see the CY 2010 PFS proposed rule (74 FR 33537) and final rule with comment period (74 FR 61758).

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), malpractice RVUs for new and revised codes effective before the next five-year review of malpractice RVUs (for example, effective CY 2011 through CY 2014, assuming that the next review of malpractice RVUs occurs for CY 2015) are determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjust (or ''scale'') the malpractice RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work value (or, if greater, the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code is 10 percent higher than the work RVU for its source code, the malpractice RVU for the revised code would be increased by 10 percent over the source code malpractice RVU. This approach presumes the same risk factor for the new/revised code and source code but

uses the work RVU for the new/revised code to adjust for the difference in risk attributable to the variation in work between the two services.

For CY 2014, we will continue our current approach for determining malpractice RVUs for new/revised codes. We will publish a list of new/revised codes and the malpractice crosswalks used for determining their malpractice RVUs in the final rule with comment period. The CY 2014 malpractice RVUs for new/revised codes will be implemented in the CY 2014 PFS final rule with comment period. These RVUs will be subject to public comment. They will then be finalized in the CY 2015 PFS final rule with comment period.

D. Medicare Economic Index (MEI)

1. Revising of the Medicare Economic Index (MEI)

a. Background

The Medicare Economic Index (MEI) is authorized under section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. Beginning July 1, 1975, and continuing through today, the MEI has met this requirement by reflecting the weighted-average annual price change for various inputs involved in furnishing physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide, private nonfarm business multifactor productivity. This index is comprised of two broad categories: (1) Physicians' own time; and (2) physicians' practice expense (PE).

The current form of the MEI was described in the November 25, 1992 **Federal Register** (57 FR 55896) and was based in part on the recommendations of a Congressionally-mandated meeting of experts held in March 1987. Since that time, the MEI has been updated or revised on four instances. First, the MEI was rebased in 1998 (63 FR 58845), which moved the cost structure of the index from 1992 data to 1996 data. Second, the methodology for the productivity adjustment was revised in the CY 2003 PFS final rule with comment period (67 FR 80019) to reflect the percentage change in the 10-year moving average of economy-wide private nonfarm business multifactor productivity. Third, the MEI was rebased in 2003 (68 FR 63239), which moved the cost structure of the index from 1996 data to 2000 data. Fourth, the MEI was rebased in 2011 (75 FR 73262), which moved the cost structure of the index from 2000 data to 2006 data.

The terms ''rebasing'' and ''revising'', while often used interchangeably, actually denote different activities. Rebasing refers to moving the base year for the structure of costs of an input price index, while revising relates to other types of changes such as changing data sources, cost categories, or price proxies used in the input price index. For CY 2014, we are proposing to revise the MEI based on the recommendations of the MEI Technical Advisory Panel (TAP). We are not rebasing the MEI and will continue to use the data from 2006 to estimate the cost weights, since these are the most recently available, relevant, and complete data we have available to develop these weights. In the following sections of this proposed rule, we detail our proposals regarding reorganization of cost categories, our rationale for selecting the price proxies in the MEI, and the results of the proposed revisions to the MEI based on the MEI TAP recommendations.

b. MEI Technical Advisory Panel (TAP) Recommendations

In the CY 2011 PFS final rule (77 FR 68892), we proposed to convene a MEI TAP that would review all aspects of the MEI, including the inputs, input weights, price-measurement proxies, and productivity adjustment. The MEI TAP was to assess the relevance and accuracy of these inputs to current physician practices. The MEI TAP's analysis and recommendations would be considered in future rulemaking to ensure that the MEI accurately and appropriately meets its intended statutory purpose.

The MEI TAP was established by the Secretary under 42 U.S.C. 217a and was governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463, enacted on October 6, 1972), as amended, 5 U.S.C. App. The Panel's deliberations were made in accordance with the FACA, which means that the meetings were conducted in public and stakeholders were given the opportunity to share their evidence and views with panel members.

The MEI TAP consisted of five members and held three meetings in 2012: May 21; June 25; and July 11. It produced 8 findings and 13 recommendations for consideration by CMS. Background on the MEI TAP members, meeting transcripts for all three meetings, and the MEI TAP's final report, including all findings and recommendations are available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEITAP.html.* It is possible to implement some of the recommendations immediately, while more in-depth research is required to implement several of the recommendations.

For CY 2014, we are proposing to implement 10 of the 13 recommendations made by the MEI TAP. These proposed changes only involve revising the MEI categories, cost shares, and price proxies. Again, we are not proposing to rebase the MEI at this time since the MEI TAP concluded that there is not a reliable, ongoing source of data to maintain the MEI. After acknowledging that there are no additional data to support further rebasing of the MEI at this time, the MEI TAP recommended that CMS' Office of the Actuary (OACT) identify and evaluate additional data sources that may allow for more frequent updates to the MEI's cost categories and their respective weights. Some of the possible data sources the MEI TAP suggested we consider are:

- The Medical Group Management Association's (MGMA) Cost Survey
- The Bureau of the Census Services Annual Survey (SAS)
- Pending feasibility, a CMS survey, possibly conducted jointly with the American Medical Association, that focuses exclusively on physician expenses as they relate to the MEI. The Panel notes that the lead time to conceive, develop, fund, and administer such a survey would likely be considerable.
- Alternatively, and again pending feasibility, CMS could obtain more robust data by means of detailed formal cost reports based on a methodologically sound sample of physician practices. Whether the degree of improvement in the MEI would warrant the cost associated with the process would be an important consideration.

As such, we will continue to investigate possible data sources, including an assessment of whether using self-employed physician data for the MEI cost weights, continues to be the most appropriate approach.

c. Overview of Proposed Revisions

The MEI was last rebased and revised in the CY 2011 PFS final rule with comment period (75 FR 73262–73275). The current base year for the MEI is 2006, which means that the cost weights in the index reflect physicians' expenses in 2006. The details of the methodology used to determine the 2006 cost shares were provided in the CY 2011 PFS

proposed rule and finalized in the CY 2011 PFS final rule with comment period (75 FR 40087 and 75 FR 73262, respectively). We are proposing to make the following revisions to the 2006-based MEI:

(1) Reclassify and Revise Certain Cost Categories

- Reclassify expenses for non-physician clinical personnel that can bill independently from non-physician compensation to physician compensation.
- Revise the physician wage and benefit split so that the cost weights are more in line with the definitions of the price proxies used for each category.
- Add an additional subcategory under non-physician compensation for health-related workers.
- Create a new cost category called ''All Other Professional Services'' that includes expenses covered in the current MEI categories: ''All Other Services'' and ''Other Professional Expenses.'' The proposed ''All Other Professional Services'' category would be further disaggregated into appropriate occupational subcategories.
- Create an aggregate cost category called ''Miscellaneous Office Expenses'' that would include the expenses for ''Rubber and Plastics,'' ''Chemicals,'' ''All Other Products,'' and ''Paper.''

(2) Revise Price Proxies

- Revise the price proxy for physician wages and salaries from the Average Hourly Earnings (AHE) for the Total Private Nonfarm Economy for Production and Nonsupervisory Workers to the ECI for Wages and Salaries, Professional and Related Occupations, Private Industry.
- Revise the price proxy for physician benefits from the ECI for Benefits for the Total Private Industry to the ECI for Benefits, Professional and Related Occupations, Private Industry.
- Use the ECI for Wages and Salaries and the ECI for Benefits of Hospital, Civilian workers (private industry) as the price proxies for the new category of non-physician health-related workers.
- Use ECIs to proxy the Professional Services occupational subcategories that reflect the type of professional services purchased by physicians' offices.
- Revise the price proxy for the fixed capital category from the CPI for Owners' Equivalent Rent of Residences to the PPI for Lessors of Nonresidential Buildings (NAICS 53112).

d. Revising Expense Categories in the MEI

The MEI is used as part of the Sustainable Growth Rate (SGR) methodology to update the PFS and represents the price component of that update. The proposed expense categories in the MEI, along with their respective weights, are primarily derived from data collected in the 2006 AMA Physician Practice Information Survey (PPIS) for self-employed physicians representing 42 medical specialties and selected self-employed non-Medical Doctor (non-MD) specialties. Data for non-MD specialties were collected in a supplemental survey of the PPIS survey questionnaire. We included the data from the following non-medical specialties in the MEI cost weight calculations (optometrists, oral surgeons, podiatrists, and chiropractors) specialties in the MEI cost weight calculations consistent with the definition of the term ''physician'' in section 1861(r) of the Act. In summary, the term ''physician'' when used in connection with the performance of functions or actions an individual is legally authorized to perform means the following: (1) A doctor of medicine or osteopathy; (2) a doctor of dental surgery or of dental medicine; (3) a doctor of podiatric medicine; (4) a doctor of optometry; or (5) a chiropractor. For a complete definition, please see section 1861(r) of the Act. We are not proposing to change the data source we used to establish the major MEI cost weights, and therefore, we propose to continue to use of the 2006 AMA PPIS physician expense data at this time. Data for the dental medicine specialty are not included in the weights since the PPIS supplemental collection effort did not survey this specialty.

We are not proposing any changes in the methodology for estimating the cost shares as finalized in the CY 2011 PFS final rule with comment period (75 FR 73263–73267). For CY 2014, we are proposing to revise the classification of certain expenses within the 2006-based MEI. The following sections describe the details of the proposed revisions for each of the categories and the rationale for the proposed changes. We also provide the Panel recommendation that is the impetus for each of the proposed revisions.

(1) Overall MEI Cost Weights

Table 14 lists the set of mutually exclusive and exhaustive cost categories and weights that make up the proposed revised MEI as compared to the current MEI cost categories.

The physician compensation cost weight under the proposed revised MEI is 2.600 percentage points higher than the physician compensation weight in the current MEI. This occurs because of the proposed reclassification of expenses for non-physician clinical staff that can bill independently from non-physician compensation to physician compensation. This change lowers the PE cost weight by 2.600 percent as well, all of which comes from a lower weight for non-physician compensation. The remaining MEI cost weights are unchanged.

The proposed revised MEI includes four new detailed cost categories and two new sub-aggregate cost categories. The proposed new detailed cost categories are:

- Health-related, non-physician wages and salaries.
- Professional, scientific, and technical services.
- Administrative support and waste management services.
- All other services.

The proposed new sub-aggregate categories are:

- Non-health, non-physician wages.
- Miscellaneous office expenses.

The proposed revised MEI excludes two sub-aggregate categories that were included in the current 2006-based MEI. The sub-aggregate categories we propose to remove are:

- Office expenses.
- Drugs & supplies.

TABLE 14—PROPOSED REVISED 2006 MEI COST CATEGORIES AND, WEIGHTS COMPARED TO THE CURRENT 2006 MEI COST CATEGORIES AND WEIGHTS

Current MEI (2006 = 100), finalized in the CY2011 PFS final rule		Proposed revised MEI (2006 = 100), CY2014 PFS proposed rule	
Cost category	Current weights (percent)	Revised weights (percent)	Revised cost category
Physician Compensation	48.266	50.866	Physician Compensation.
Wages and Salaries	43.881	43.641	Wages and Salaries.

TABLE 14—PROPOSED REVISED 2006 MEI COST CATEGORIES AND, WEIGHTS COMPARED TO THE CURRENT 2006 MEI COST CATEGORIES AND WEIGHTS—Continued

Current MEI (2006 = 100), finalized in the CY2011 PFS final rule		Proposed revised MEI (2006 = 100), CY2014 PFS proposed rule	
Cost category	Current weights (percent)	Revised weights (percent)	Revised cost category
Benefits	4.386	7.225	Benefits.
Practice Expense	51.734	49.134	Practice Expense.
Non-physician compensation	19.153	16.553	Non-physician compensation.
Non-physician wages	13.752	11.885	Non-physician wages.
		7.249	Non-health, non-physician wages.
P&T	6.006	0.800	Professional and Related.
Management	1.446	1.529	Management.
Clerical	4.466	4.720	Clerical.
Services	1.834	0.200	Services.
		4.636	Health related, non-physician wages.
Non-physician benefits	5.401	4.668	Non-physician benefits.
Other Practice Expense	26.308	32.581	Other Practice Expense.
Office expenses	20.035		
Utilities	1.266	1.266	Utilities.
		2.478	Miscellaneous Office Expenses.
Chemicals	0.723	0.723	Chemicals.
Paper	0.656	0.656	Paper.
Rubber & Plastics	0.598	0.598	Rubber & Plastics.
		0.500	All other products.
Telephone	1.501	1.501	Telephone.
Postage	0.898	0.898	Postage.
All other services	3.581	8.095	All Other professional services.
		2.592	Professional, scientific, & technical services.
		3.052	Administrative support & waste management.
		2.451	All other services.
All other products	0.500		
Capital	10.310	10.310	Capital.
Fixed Capital	8.957	8.957	Fixed Capital.
Moveable Capital	1.353	1.353	Moveable Capital.
Professional Liability Insurance	4.295	4.295	Professional Liability Insurance.
Medical Equipment	1.978	1.978	Medical Equipment.
Drugs and Supplies	1.760		
Prescription Drugs	0.000		
Medical supplies	1.760	1.760	Medical supplies.
Other Professional Expenses	4.513		
All other	4.513		
Total MEI	100.000	100.000	Total MEI.

* The term (2006 = 100) refers to the base year of the MEI

(2) Physician Compensation (Own time).

The component of the MEI that reflects the physician's own time is represented by the net income portion of business receipts. The 2006 cost weight associated with the physician's own time (otherwise referred to as the Physician's Compensation cost weight) is based on 2006 AMA PPIS data for mean physician net income (physician compensation) for self-employed physicians and for the selected self-employed specialties referenced previously in this rule. Expenses for employed physician compensation are combined with expenses for self-employed physician compensation to obtain an aggregate Physician Compensation cost weight. Based on this methodology, the Physician Compensation cost weight in the current MEI is 48.266 percent.

As discussed in the CY 2011 PFS final rule with comment period (75 FR 73265), when determining this weight, we classified the expenses for non-physician clinical staff that can bill Medicare independently under non-physician compensation, which is where these expenses have historically been apportioned in the MEI. The AMA PPIS survey question that collected the data for the clinical personnel who can independently bill, such as nurse practitioners, physician assistants, and other clinical personnel, captured these expenses under non-physician compensation. Additionally, prior AMA surveys captured these expenses as non-physician compensation costs.

The Panel reviewed this methodology and Recommendation 3.2 was that:

''OACT evaluate the appropriate classification of the expenses associated with non-physician clinical staff who can bill Medicare independently. Among the factors OACT should consider are:

- Any definition of 'physicians' that exists under current law in relation to the Medicare PFS and whether these definitions might limit OACT's ability to make changes;
- Whether time for non-physician staff who can bill independently is included among the inputs to the PE RVU methodology under the Medicare PFS (that is, is the treatment of this input under the PE RVU methodology consistent with that under the MEI);
- Whether there is any evidence these staff do not spend the majority of their time providing 'physicians' services' as defined by Medicare; and
- The extent to which those who can bill independently actually do so.''

We are proposing to reclassify these expenses to physician compensation for several reasons:

- These types of practitioners furnish services that are similar to those furnished by physicians.
- If billing independently, these practitioners would be paid at a percentage of the physicians' services or in certain cases at the same rate as physicians.
- The expenses related to the work components for the RVUs would include work from clinical staff that can bill independently. Therefore, it would improve consistency with the RVU payments to include these expenses as physician compensation in the MEI.

The effect of moving the expenses related to clinical staff that can bill independently is to increase the physician compensation cost share by 2.600 percentage points and reduces non-physician compensation costs by the same amount. The physician compensation cost share for the proposed revised MEI is 50.866 percent compared to the physician compensation cost share of 48.266 percent in the current MEI.

Within the physician compensation cost weight, the MEI includes a separate weight for wages and salaries and a separate weight for benefits. Under the current 2006-based MEI, the ratio for wages and salaries, and benefits was calculated using data from the PPIS. Self-employed physician wages and salaries accounted for 92.3 percent of physician earnings while physician benefits accounted for the remaining 7.8 percent. For employed physician payroll, the distributions for wages and salaries, and benefits for 2006 were 85.8 percent and 14.2 percent, respectively. This ratio was determined by calculating a weighted average of available IRS Statistics of Income (SOI) data for partnerships, corporations, and S-corporations specific to physicians and outpatient care centers. Combining the information on self-employed and employed physicians produced a physician wages & salaries cost weight of 43.880 percent and a physician benefits cost weight of 4.386 percent, in the current MEI.

Recommendation 3.1 stated:

> The Panel recommends that OACT revise the Physician Wages and Salaries and Physician Benefit cost weights in the 2006-based MEI. OACT should determine the cost weights for wages and benefits to ensure they are consistent with the definitions in the Employment Cost Index. Specifically, OACT should consider estimating the proportion of the Physician Wages and Salaries cost weight associated with physicians' retirement benefits, and reclassifying that percentage into the Physician Benefits cost weight to be consistent with the costs included in the ECI for Wages and Salaries and the ECI for Benefits price proxies. Evaluation of the PPIS data determined that retirement benefits were included in the Physician Wages and Salaries cost weight while the associated price change is currently reflected in the ECI for Benefits.

We are proposing to revise the wage and benefit split used for physician compensation. Specifically, we are proposing to apply the distribution from the SOI data to both self-employed and employed physician compensation. In reviewing the detailed AMA PPIS survey questions, it was clear that self-employed physician benefits were mainly comprised of insurance costs while other benefits such as physician retirement, paid leave, and payroll taxes were likely included in physician wages and salaries.

By definition, the price proxy used for physician benefits, which is an Employment Cost Index (ECI) concept, includes retirement savings. Thus, using the AMA PPIS data produces a definitional inconsistency between the cost weight and the price proxy. Therefore, we propose to use the data on wages and salaries, and employee benefits from the SOI for Offices of Physicians and Dentists for partnerships and corporations for both self-employed and employed physicians. From the SOI data, benefit expenses were estimated by summing the partnership data for retirement plans and employee benefit programs with corporation data for pension, profit-sharing plans and employee benefit programs. For 2006, the split between wages and salaries, and benefits was 85.8 percent and 14.2 percent, respectively. Retirement/pension plans account for about 60 percent of total benefits. The SOI data do not classify paid leave and supplemental pay as a benefit.

Combining the impact of classifying compensation for non-physicians that can bill independently as physician compensation with the use of the SOI data, the physician wages and salary cost share in the proposed revised MEI is lower than the current MEI by 0.240 percentage points. These two methodological changes result in an increase in the physician benefit cost share in the proposed revised MEI of 2.839 percentage points. As a result, the physician wages and salary cost share for the proposed revised MEI is 43.641 percent and the physician benefit cost share for the proposed revised MEI is 7.225 percent.

(3) Physician's Practice Expenses

To determine the PE cost weights, we use mean expense data from the 2006 PPIS survey. The derivation of the weights and categories for practice expenses is the same as finalized in the CY 2011 PFS final rule with comment period (75 FR 73264–73267), except where noted below.

(a) Non-physician Employee Compensation

The cost weight for Non-physician Employee Compensation was developed using the 2006 AMA PPIS mean expenses for these costs. As discussed previously, for CY 2014 we are proposing to exclude the expenses related to non-physician clinical staff that can bill independently from this cost category. Moving the expenses related to the clinical staff that can bill independently out of non-physician compensation costs decreases the share by 2.600 percentage points. The non-physician compensation cost share for the proposed revised MEI is 16.553 percent compared to the current physician compensation cost share of 19.153 percent.

We are proposing to use the same method as finalized in the CY 2011 PFS final rule to split the non-physician compensation between wages and benefits. For reference, we use 2006 BLS Employer Costs for Employee Compensation (ECEC) data for the Health Care and Social Assistance (private industry). Data for 2006 in the ECEC for Health Care and Social Assistance indicate that wages and benefits are 71.8 percent and 28.2 percent of compensation, respectively. The non-physician wage and benefit cost shares for the proposed revised MEI are 11.885 percent and 4.668 percent, respectively; for the current MEI, the non-physician wage and benefit cost shares are 13.752 percent and 5.401 percent, respectively.

The current 2006-based MEI further disaggregated the non-physician wages into four occupational subcategories, the details of this method can be found in 75 FR 73264–73265. The MEI TAP Recommendation 4.4 stated:

> ''The Panel recommends the disaggregation of the Non-Physician Compensation costs to include an additional category for health-related workers. This disaggregation would allow for health-related workers to be separated from non-health-related workers. CMS should rely directly on PPIS data to estimate the health-related non-physician compensation cost weights. The non-health, non-physician wages should be further disaggregated based on the Current Population Survey and Occupational Employment Statistics data.''

We propose to implement this recommendation using expenses reported on the AMA PPIS for non-

physician, non-health-related workers. The survey question asks for the expenses for: ''Non-clinical personnel involved primarily in administrative, secretarial or clerical activities (Including transcriptionists, medical records personnel, receptionists, schedulers and billing staff, coding staff, information technology staff, and custodial personnel).'' The non-physician, non-health-related wage cost share for the proposed revised MEI is 7.249 percent.

For wage costs of non-physician, health-related workers, the survey question asks for the expenses for: ''Other clinical staff, including RNs, LPNs, physicists, lab technicians, x-ray technicians, medical assistants, and other clinical personnel who cannot independently bill.'' The non-physician, health-related wage cost share for the proposed revised MEI is 4.636 percent. Together the non-health and health-related, non-physician wage costs sum to be equal to the total non-physician wage share in the proposed revised MEI of 11.885 percent.

We are proposing to disaggregate the non-physician, non-health-related wage cost weight of 7.249 percent into four occupational subcategories. The methodology is similar to that finalized in the CY 2011 PFS final rule with comment period (75 FR 73264), in that we are proposing to use 2006 Current Population Survey (CPS) data and 2006 BLS Occupational Employment Statistics (OES) data to develop cost weights for wages for non-physician, non-health-related occupational groups. We determined total annual earnings for offices of physicians using employment data from the CPS and mean annual earnings from the OES. To arrive at a distribution for these separate occupational categories (Professional & Related (P&R) workers, Managers, Clerical workers, and Service workers), we determined annual earnings for each using the Standard Occupational Classification (SOC) system. We then determined the overall share of the total for each. The occupational distribution in the proposed revised MEI as well as the distribution for the 2006-based MEI is presented in Table 15.

TABLE 15—PERCENT DISTRIBUTION OF NONPHYSICIAN PAYROLL EXPENSE BY OCCUPATIONAL GROUP: PROPOSED REVISED 2006-BASED MEI AND CURRENT 2006-BASED MEI

Current MEI (2006 = 100), finalized in the CY11 PFS final rule		Proposed MEI (2006 = 100), CY14 PFS proposed rule	
Cost Category	Current MEI06 (percent)	Revised MEI06 (percent)	Revised cost category
Non-physician compensation	19.153	16.553	Non-physician compensation.
Non-physician wages	13.752	11.885	Non-physician wages.
	.....	7.249	Non-health, non-phys. wages.
P&T	6.006	0.800	Professional and Related.
Management	1.446	1.529	Management.
Clerical	4.466	4.720	Clerical.
Services	1.834	0.200	Services.
	.....	4.636	Health related, non-phys. Wages.
Non-physician benefits	5.401	4.668	Non-physician benefits.

The health-related workers were previously included mainly in the Professional and Technical and Service Categories. These proposed changes allow for health-related workers to be proxied by a health-specific ECI rather than an ECI for more general occupations.

(b) Other Practice Expense

The remaining expenses in the MEI are categorized as Other Practice Expenses. In the current 2006-based MEI we had classified other PEs in one of the following subcategories: Office Expenses; Drugs and Supplies; and All Other Professional Expenses. For CY 2014, we are proposing to disaggregate these expenses in a way consistent with the MEI TAP's recommendations, as detailed below.

We rely on the 2006 AMA PPIS data to determine the cost share for Other Practice Expenses. These expenses are the total of office expenses, medical supplies, medical equipment, Professional Liability Insurance (PLI), and all other professional expenses.

For the proposed revised 2006-based MEI, we propose to disaggregate Other Practice Expenses into 15 detailed subcategories as shown in Table 16.

TABLE 16—REVISED COST CATEGORIES FOR OTHER PRACTICE EXPENSE

Revised cost category	Revised MEI06 (percent)
Other Practice Expense	32.581
Utilities	1.266
Miscellaneous Office Expenses	2.478
Chemicals	0.723
Paper	0.656
Rubber & Plastics	0.598
All other products	0.500
Telephone	1.501
Postage	0.898
All Other professional services	8.095
Professional, Scientific, and Tech. Svcs.	2.592
Administrative and support & waste	3.052
All Other Services	2.451
Capital	10.310
Fixed	8.957
Moveable	1.353
Professional Liability Insurance	4.295
Medical Equipment	1.978
Medical supplies	1.760

For most of these categories, we use the same method as finalized in the CY 2011 PFS final rule with comment period to estimate the cost shares. In particular, the cost shares for the following categories are derived directly from expense data reported on the 2006 AMA PPIS: PLI; Medical Equipment; and Medical Supplies. In each case, the cost shares remain the same as in the current MEI. Additionally, we continue to use the Bureau of Economic Analysis (BEA) 2002—Benchmark I/O data aged to 2006 to determine the cost weights for other expenses not collected directly from the AMA PPIS. The BEA 2002-Benchmark I/O data can be accessed at the following link: *http://www.bea.gov/industry/io_benchmark.htm#2002data.*

The derivation of the cost weight for each of the detailed categories under Other Practice Expenses is provided below.

- *Utilities:* The Utilities cost weight includes expenses classified in the fuel, oil and gas, water and sewage, and electricity industries. The proposed cost weight for utilities is 1.266 percent, the same cost share as in the current MEI.

• *Miscellaneous Office Expenses:* We are proposing to include an aggregate category of detailed office expenses that were stand-alone categories in the current 2006-based MEI. During the CY 2011 PFS proposed rule comment period, several commenters expressed confusion as to the relevance of these categories to their practice costs. The MEI TAP discussed the degree of granularity needed in both the calculation and reporting of the MEI. The MEI TAP concluded that it might be prudent to collapse some of the non-labor PE categories with other categories for presentation purposes. In particular, Recommendation 3.4 was that:

''OACT report more aggregated costs under the Office Expenses cost category. In particular, reported costs associated with Rubber and Plastics, Chemicals, All Other Products, and Paper should be combined. However, the Panel believes that OACT should maintain separately the underlying details and calculations associated with these aggregated costs when applying price proxies and calculating the overall MEI and its subcomponents.'' Based on this recommendation, we are proposing to add an aggregate category to the MEI that includes the expenses for paper, chemicals, rubber and plastics, and all other products. The cost shares for paper, chemicals, rubber and plastics, and all other products remain the same for the proposed revised MEI as in the current MEI.''

• *Telephone:* The telephone cost weight includes expenses classified in the telecommunications (accounting for the majority of the telephone expenses) and cable industries. The cost weight for Telephone services is 1.501 percent in the proposed revised MEI, the same cost share as in the current MEI.

• *Postage:* The Postage cost weight includes postal service expenses. The cost weight for Postage is 0.898 percent in the proposed revised MEI, the same cost share as in the current MEI.

• *All Other Services:* We propose to combine the All Other Services cost weight and All Other Professional Expenses into a single cost category. The proposed weight for the All Other Professional Services category is 8.095 percent, which is the sum of the current MEI weight for All Other Services (3.581 percent) and All Other Professional Expenses (4.513 percent), is more in line with the GPCI Purchased Services index as finalized in the CY2012 PFS final rule with comment period (76 FR 73085). The TAP Recommendation 3.3 was that

''OACT create a new cost category entitled Professional Services that should consist of the All Other Services cost category (and its respective weight) and the Other Professional Expenses cost category (and its respective weight). The Panel further recommends that this category be disaggregated into appropriate occupational categories consistent with the relevant price proxies.''

We propose to combine the ''Other Professional Expenses'' and ''All Other Services'' cost weights of the 2006-based MEI and further disaggregate the 8.095 percent of expenses into more detail based on the BEA I–O data, allowing for specific cost weights for services such as contract billing services, accounting, and legal services. We considered various levels of aggregation; however, in considering the level of aggregation, the available corresponding price proxies must be considered. Given the price proxies that are available from the ECI, we propose to disaggregate these expenses into three categories:

• *NAICS 54 (Professional, Scientific, and Technical Services):* The Professional, Scientific, and Technical Services sector comprises establishments that specialize in performing professional, scientific, and technical activities for others. These activities require a high degree of expertise and training. The establishments in this sector specialize according to expertise and provide these services to clients in a variety of industries, including but not limited to: legal advice and representation; accounting, and payroll services; computer services; management consulting services; and advertising services and have a 2.592 percent weight.

• *NAICS 56 (Administrative and Support and Waste Management and Remediation Services):* The Administrative and Support and Waste Management and Remediation Services sector comprises establishments performing routine support activities for the day-to-day operations of other organizations. The establishments in this sector specialize in one or more of these support activities and provide these services to clients in a variety of industries including but not limited to: office administration; temporary help services; security services; cleaning and janitorial services; and trash collection services. These services have a 3.052 percent weight.

• *All Other Services, a residual category of these expenses:* The residual All Other Services cost category is mostly comprised of expenses associated with service occupations, including but not limited to: Lab and blood specimen transport; catering and food services; collection company services; and dry cleaning services and have a 2.451 percent weight.

++ *Fixed Capital:* The Fixed Capital cost weight includes expenses for building leases and depreciation. The cost weight for Fixed Capital is 8.957 percent in the proposed revised MEI, the same cost share as in the current MEI.

++ *Moveable Capital:* The Moveable Capital cost weight includes expenses for non-medical equipment including but not limited to, computer equipment and software, as well as the rental and leasing of automotive and industrial machinery equipment. The cost weight for Moveable Capital is 1.353 percent in the proposed revised MEI, the same cost share as in the current MEI.

++ *Professional Liability Insurance (PLI):* The weight for PLI expense was derived from the 2006 AMA survey and was calculated as the mean PLI expense expressed as a percentage of total expenses. The cost weight for PLI is 4.295 percent in the proposed revised MEI, the same cost share as in the current MEI.

++ *Medical Equipment Expenses:* The proposed weight for Medical Equipment was calculated using the 2006 AMA PPIS mean expense data. The cost weight for Medical Equipment Expenses is 1.978 percent in the proposed revised MEI, the same cost share as in the current MEI.

++ *Medical Supplies Expenses:* The proposed weight for Medical Supplies was calculated using the 2006 AMA PPIS mean expense data. The cost weight for Medical Supplies Expenses is 1.760 percent in the proposed revised MEI, the same cost share as in the current MEI.

2. Selection of Price Proxies for Use in the MEI

After developing the cost category weights for the proposed revised 2006-based MEI, we reviewed all the price proxies based on the recommendations from the MEI TAP. As was the case in the development of the current 2006-based MEI, most of the proxy measures we considered are based on BLS data and are grouped into one of the following four categories:

• *Producer Price Indices (PPIs):* PPIs measure price changes for goods sold in markets other than retail markets. These fixed-weight indexes are measures of price change at the intermediate or final stage of production. They are the preferred proxies for physician purchases as these prices appropriately reflect the product's first commercial transaction.

• *Consumer Price Indices (CPIs):* CPIs measure change in the prices of final

goods and services bought by consumers. Like the PPIs, they are fixed weight indexes. Since they may not represent the price changes faced by producers, CPIs are used if there are no appropriate PPIs or if the particular expenditure category is likely to contain purchases made at the final point of sale.

• *Employment Cost Indices (ECIs) for Wages & Salaries:* These ECIs measure the rate of change in employee wage rates per hour worked. These fixed-weight indexes are not affected by employment shifts among industries or occupations and thus, measure only the pure rate of change in wages.

• *Employment Cost Indices (ECIs) for Employee Benefits:* These ECIs measure the rate of change in employer costs of employee benefits, such as the employer's share of Social Security taxes, pension and other retirement plans, insurance benefits (life, health, disability, and accident), and paid leave. Like ECIs for wages & salaries, the ECIs for employee benefits are not affected by employment shifts among industries or occupations.

When choosing wage and price proxies for each expense category, we evaluate the strengths and weaknesses of each proxy variable using the following four criteria.

• *Relevance:* The price proxy should appropriately represent price changes for specific goods or services within the expense category. Relevance may encompass judgments about relative efficiency of the market generating the price and wage increases.

• *Reliability:* If the potential proxy demonstrates a high sampling variability, or inexplicable erratic patterns over time, its viability as an appropriate price proxy is greatly diminished. Notably, low sampling variability can conflict with relevance—since the more specifically a price variable is defined (in terms of service, commodity, or geographic area), the higher the possibility of high sampling variability. A well-established time series is also preferred.

• *Timeliness of actual published data:* For greater granularity and the need to be as timely as possible, we prefer monthly and quarterly data to annual data.

• *Public availability:* For transparency, we prefer to use data sources that are publicly available.

Below we discuss the price and wage proxies for each cost category of the proposed revised 2006-based MEI (as shown in Table 17). We will continue to use the same price proxies as those used in the 2006-based MEI except as noted below.

a. Physician Compensation (Physician's Own Time)

(1) Physician Wages and Salaries

Based on recommendations from the MEI TAP, we are proposing to use the ECI for Wages and Salaries for Professional and Related Occupations (Private Industry) (BLS series code CIU2020000120000I) to measure price growth of this category in the proposed revised 2006-based MEI. The current 2006-based MEI used Average Hourly Earnings (AHE) for Production and Non-Supervisory Employees for the Private Nonfarm Economy.

The MEI TAP had two recommendations concerning the price proxy for physician Wages and Salaries. The first recommendation from the MEI TAP was Recommendation 4.1, which was that: ''. . . OACT revise the price proxy associated with Physician Wages and Salaries from an Average Hourly Earnings concept to an Employment Cost Index concept.'' AHEs are calculated by dividing gross payrolls for wages and salaries by total hours. The AHE proxy was representative of actual changes in hourly earnings for the nonfarm business economy, including shifts in employment mix. The recommended alternative, the ECI concept, measures the rate of change in employee wage rates per hour worked. ECIs measure the pure rate of change in wages by industry and/or occupation and are not affected by shifts in employment mix across industries and occupations. The MEI TAP thought that the ECI concept better reflected physician wage trends compared to the AHE concept.

The second recommendation related to the price proxy for physician wages and salaries was Recommendation 4.2, which was that:

> CMS revise the price proxy associated with changes in Physician Wages and Salaries to use the Employment Cost Index for Wages and Salaries, Professional and Related, Private Industry. The Panel believes this change would maintain consistency with the guidance provided in the 1972 Senate Finance Committee report titled 'Social Security Amendments of 1972,' which stated that the index should reflect changes in practice expenses and 'general earnings.' In the event this change would be determined not to meet the legal requirement that the index reflect ''general earnings,'' the Panel recommends replacing the current proxy with the Employment Cost Index for Wages and Salaries, All Workers, Private Industry. The Panel believed this change would maintain consistency with the guidance provided in the 1972 Senate Finance Committee report titled ''Social Security Amendments of 1972,'' which stated that the index should reflect changes in practice expenses and ''general earnings.'' [1]

We agree that switching the proxy to the ECI for Wages and Salaries for Professional and Related Occupations would be consistent with the authority provided in the statute and reflect a wage trend more consistent with other professionals that receive advanced training. Additionally, we believe the ECI is a more appropriate concept than the AHE because it can isolate wage trends without being impacted by the change in the mix of employment.

(2) Physician Benefits

The MEI TAP states in Recommendation 4.3 that, ''. . . any change in the price proxy for Physician Wages and Salaries be accompanied by the selection and incorporation of a Physician Benefits price proxy that is consistent with the Physician Wages and Salaries price proxy.'' We are proposing to use the ECI for Benefits for Professional and Related Occupations (Private Industry) to measure price growth of this category in the proposed revised 2006-based MEI. The ECI for Benefits for Professional and Related Occupations is derived using BLS's Total Compensation for Professional and Related Occupations (BLS series ID CIU2010000120000I) and the relative importance of wages and salaries within total compensation. We believe this series is technically appropriate because it better reflects the benefit trends for professionals requiring advanced training. The current 2006-based MEI market basket used the ECI for Total Benefits for the Total Private Industry.

b. Practice Expense

(1) Non-Physician Employee Compensation

(a) Non-Physician Wages and Salaries

(i) Non-Physician, Non-Health-Related Wages and Salaries

• *Professional and Related:* We will continue using the ECI for Wages and Salaries for Professional and Related Occupation (Private Industry) (BLS series code CIU2020000120000I) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Management:* We will continue using the ECI for Wages and Salaries for Management, Business, and Financial (Private Industry) (BLS series code CIU2020000110000I) to measure the price growth of this cost category. This

[1] U.S. Senate, Committee on Finance, *Social Security Amendments of 1972.* ''Report of the Committee on Finance United States Senate to Accompany H.R. 1,'' September 26, 1972, p. 191.

is the same proxy used in the current 2006-based MEI.

• *Clerical:* We will continue using the ECI for Wages and Salaries for Office and Administrative Support (Private Industry) (BLS series code CIU20200002200001) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Services:* We will continue using the ECI for Wages and Salaries for Service Occupations (Private Industry) (BLS series code CIU20200003000001) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

(ii) Non-Physician, Health-Related Wages and Salaries

In Recommendation 4.4, the MEI TAP ''. . . recommend[ed] the disaggregation of the Non-Physician Compensation costs to include an additional category for health-related workers. This disaggregation would allow for health-related workers to be separated from non-health-related workers. CMS should rely directly on PPIS data to estimate the health-related non-physician compensation cost weights. The non-health, non-physician wages should be further disaggregated based on the Current Population Survey and Occupational Employment Statistics data. The new health-related cost category should be proxied by the ECI, Wages and Salaries, Hospital (NAICS 622), which has an occupational mix that is reasonably close to that in physicians' offices. The Non-Physician Benefit category should be proxied by a composite benefit index reflecting the same relative occupation weights as the non-physician wages.'' We are proposing to use the ECI for Wages and Salaries for Hospital Workers (Private Industry) (BLS series code CIU20262200000001) to measure the price growth of this cost category in the proposed revised 2006-based MEI. The ECI for Hospital workers has an occupational mix that approximates that in physicians' offices. This cost category was not broken out separately in the current 2006-based MEI.

(b) Non-Physician Benefits

We will continue using a composite ECI for non-physician employee benefits in the proposed revised 2006-based MEI. However, we are proposing to expand the number of occupations from four to five by adding detail on Non-Physician Health-Related Benefits. The weights and price proxies for the composite benefits index will be revised to reflect the addition of the new category. Table 17 lists the five ECI series and corresponding weights used to construct the proposed revised composite benefit index for non-physician employees in the proposed revised 2006-based MEI.

TABLE 17—CMS COMPOSITE PRICE INDEX FOR NON-PHYSICIAN EMPLOYEE BENEFITS IN THE PROPOSED REVISED 2006-BASED MEI

ECI Series	2006 Weight (%)
Benefits for Professional and Related Occupation (Private Industry)	7
Benefits for Management, Business, and Financial (Private Industry)	12
Benefits for Office and Administrative Support (Private Industry)	40
Benefits for Service Occupations (Private Industry)	2
Benefits for Hospital Workers (Private Industry)	39

(3) Other Practice Expense

(a) All Other Professional Services

As discussed previously, MEI TAP Recommendation 3.3 was that:

''. . . OACT create a new cost category entitled Professional Services that should consist of the All Other Services cost category (and its respective weight) and the Other Professional Expenses cost category (and its respective weight). The Panel further recommends that this category be disaggregated into appropriate occupational categories consistent with the relevant price proxies.'' We are proposing to implement this recommendation in the proposed revised 2006-based MEI using a cost category titled ''All Other Professional Services.'' Likewise, the MEI TAP stated in Recommendation 4.7 that ''. . . price changes associated with the Professional Services category be proxied by an appropriate blend of Employment Cost Indexes that reflect the types of professional services purchased by physician offices.'' We agree with this recommendation and are proposing to the use the following price proxies for each of the new occupational categories:

• *Professional, Scientific, and Technical Services:* We are proposing to use the ECI for Total Compensation for Professional, Scientific, and Technical Services (Private Industry) (BLS series code CIU20154000000001) to measure the price growth of this cost category. This cost category was not broken out separately in the current 2006-based MEI.

• *Administrative and Support Services:* We are proposing to use the ECI for Total Compensation for Administrative, Support, Waste Management, and Remediation Services (Private Industry) (BLS series code CIU20156000000001) to measure the price growth of this cost category. This cost category was not broken out separately in the current 2006-based MEI.

• *All Other Services:* We are proposing to use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU20100003000001) to measure the price growth of this cost category.

(b) Miscellaneous Office Expenses

• *Chemicals:* We will continue using the PPI for Other Basic Organic Chemical Manufacturing (BLS series code #PCU32519–32519) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Paper:* We will continue using the PPI for Converted Paper and Paperboard (BLS series code #WPU0915) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Rubber & Plastics:* We will continue using the PPI for Rubber and Plastic Products (BLS series code #WPU07) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *All Other Products:* We will continue using the CPI–U for All Products less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Utilities:* We will continue using the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Telephone:* We will continue using the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Postage:* We will continue using the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Fixed Capital:* In Recommendation 4.5, ''The Panel recommends using the Producer Price Index for Lessors of Nonresidential Buildings (NAICS 53112) for the MEI Fixed Capital cost category as it represents the types of

fixed capital expenses most likely faced by physicians. The Panel noted the volatility in the index, which is greater than the Consumer Price Index for Owners' Equivalent Rent of Residences. This relative volatility merits ongoing monitoring and evaluation of alternatives.'' We are proposing to use the PPI for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category in the proposed revised 2006-based MEI. The current 2006-based MEI used the CPI for Owner's Equivalent Rent. We believe the PPI for Lessors of Nonresidential Buildings is more appropriate as fixed capital expenses in physician offices should be more congruent with trends in business office space costs than residential costs.

• *Moveable Capital:* In Recommendation 4.6, the MEI TAP states that ''. . . CMS conduct research into and identify a more appropriate price proxy for Moveable Capital expenses. In particular, the Panel believes it is important that a proxy reflect price changes in the types of non-medical equipment purchased in the production of physicians' services, as well as the price changes associated with Information and Communication Technology expenses (including both hardware and software).'' We intend to continue to investigate possible data sources that could be used to proxy the physician expenses related to moveable capital in more detail. However, we will continue to use the PPI for Machinery and Equipment (series code WPU11) to measure the price growth of this cost category in the proposed revised 2006-based MEI. This is the same proxy used in the current 2006-based MEI.

• *Professional Liability Insurance:* Unlike the other price proxies based on data from BLS and other public sources, the proxy for PLI is based on data collected directly by CMS from a sample of commercial insurance carriers. The MEI TAP discussed the methodology of the CMS PLI index, as well as considered alternative data sources for the PLI price proxy, including information available from BLS and through state insurance commissioners. MEI TAP Finding 4.3 states:

''The Panel finds the CMS-constructed professional liability insurance price index used to proxy changes in professional liability insurance premiums in the MEI represents the best currently available method for its intended purpose. The Panel also believes the pricing patterns of commercial carriers, as measured by the CMS PLI index, are influenced by the same driving forces as those observable in policies underwritten by physician-owned insurance entities; thus, the Panel believes the current index appropriately reflects the price changes in premiums throughout the industry.'' Given this finding, we will continue using the CMS Physician PLI index to measure the price growth of this cost category in the proposed revised 2006-based MEI. This is the same proxy used in the current 2006-based MEI.

• *Medical Equipment:* We will continue using the PPI for Medical Instruments and Equipment (BLS series code WPU1562) as the price proxy for this category. This is the same proxy used in the current 2006-based MEI.

• *Medical Materials and Supplies:* We will continue using a blended index comprised of 50/50 blend of the PPI for Surgical Appliances (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). This is the same proxy used in the current 2006-based MEI.

TABLE 18—PROPOSED REVISED 2006-BASED MEI COST CATEGORIES, WEIGHTS, AND PRICE PROXIES

Cost category	2006 Weight (percent)	Price proxy
Total MEI	100.000	
Physician Compensation	50.866	
Wages and Salaries	43.641	ECI—Wages and salaries—Professional and Related (Private).
Benefits	7.225	ECI—Benefits—Professional and Related (Private).
Practice Expense	49.134	
Non-physician Compensation	16.553	
Non-physician Wages	11.885	
Non-health, non-physician wages	7.249	
Professional and Related	0.800	ECI—Wages And Salaries—Professional and Related (Private).
Management	1.529	ECI—Wages And Salaries—Mgmt., Business, and Finc. (Private).
Clerical	4.720	ECI—Wages And Salaries—Office and Admin. Support (Private).
Services	0.200	ECI—Wages And Salaries—Service Occupations (Private).
Health related, non-phys. Wages	4.636	ECI—Wages and Salaries—Hospital (Private).
Non-physician Benefits	4.668	Composite Benefit Index.
Other Practice Expense	32.581	
Miscellaneous Office Expenses	2.478	
Chemicals	0.723	PPI—Other Basic Organic Chemical Manufacturing.
Paper	0.656	PPI—Converted Paper and Paperboard.
Rubber and Plastics	0.598	PPI—Rubber and Plastic Products.
All other products	0.500	CPI—All Items Less Food And Energy.
Telephone	1.501	CPI—Telephone.
Postage	0.898	CPI—Postage.
All Other Professional Services	8.095	
Prof., Scientific, and Tech. Svcs	2.592	ECI—Compensation—Prof., Scientific, and Technical (Private).
Admin. and Support Services	3.052	ECI—Compensation—Admin., Support, Waste Mgmt. (Private).
All Other Services	2.451	ECI—Compensation—Service Occupations (Private).
Capital:		
Fixed Capital	8.957	PPI—Lessors of Nonresidential Buildings.
Moveable Capital	1.353	PPI—Machinery and Equipment.
Professional Liability Insurance	4.295	CMS—Professional Liability Phys. Prem. Survey.
Medical Equipment	1.978	PPI—Medical Instruments and Equipment.
Medical Supplies	1.760	Composite—PPI Surgical Appliances & CPI–U Medical Supplies.

3. Productivity Adjustment to the MEI

The MEI has been adjusted for changes in productivity since its inception. In the CY 2003 PFS final rule with comment period (67 FR 80019), we implemented a change in the way the MEI was adjusted to account for changes in productivity. The MEI used for the 2003 physician payment update incorporated changes in the 10-year moving average of private nonfarm business (economy-wide) multifactor productivity that were applied to the entire index. Previously, the index incorporated changes in productivity by adjusting the labor portions of the index by the 10-year moving average of economy-wide private nonfarm business labor productivity.

The MEI TAP was asked to review this approach. In Finding 5.1, ''[t]he Panel reviewed the basis for the current economy-wide multifactor productivity adjustment (Private Nonfarm Business Multifactor Productivity) in the MEI and finds such an adjustment continues to be appropriate. This adjustment prevents 'double counting' of the effects of productivity improvements, which would otherwise be reflected in both (i) the increase in compensation and other input price proxies underlying the MEI, and (ii) the growth in the number of physician services performed per unit of input resources, which results from advances in productivity by individual physician practices.''

Based on the MEI TAP's finding, we will continue to use the current method for adjusting the full MEI for multifactor productivity in the proposed revised 2006-based MEI. As described in the CY 2003 PFS final rule with comment period, we believe this adjustment is appropriate because it explicitly reflects the productivity gains associated with all inputs (both labor and non-labor). We believe that using the 10-year moving average percent change in economy-wide multifactor productivity is appropriate for deriving a stable measure that helps alleviate the influence that the peak (or a trough) of a business cycle may have on the measure. The adjustment will be based on the latest available historical economy-wide nonfarm business multifactor productivity data as measured and published by BLS.

4. Results of Proposed Revisions on the MEI Update

Table 19 shows the average calendar year percent change from CY 2005 to CY 2014 for both the proposed revised 2006-based MEI and the current 2006-based MEI. The average annual percent change in the proposed revised 2006-based MEI is 0.1 percent lower than the current 2006-based MEI over the 2005–2013 period. On an annual basis over this period, the differences vary by up to plus or minus 0.7 percentage points. In the two most recent years (CY 2012 and CY 2013), the annual percent change in the proposed revised 2006-based MEI was within 0.1 percentage point of the percent change in the current 2006-based MEI. The majority of these differences over the historical period can be attributed to the revised price proxy for physician wages and salaries and benefits and the revised price proxy for fixed capital.

TABLE 19—ANNUAL PERCENT CHANGE IN THE PROPOSED REVISED 2006-BASED MEI, NOT INCLUDING PRODUCTIVITY ADJUSTMENT AND THE CURRENT 2006-BASED MEI, NOT INCLUDING PRODUCTIVITY ADJUSTMENT *

Update year	Proposed revised 2006-based MEI excl. MFP	Current 2006-based MEI, excl. MFP
CY 2005	3.8	3.1
CY 2006	4.0	3.3
CY 2007	3.2	3.2
CY 2008	3.2	3.4
CY 2009	2.9	3.1
CY 2010	2.4	2.8
CY 2011	0.9	1.6
CY 2012	1.7	1.8
CY 2013	1.7	1.8
Avg. Change for CYs 2005–2013	2.6	2.7

* Update year based on historical data through the second quarter of the prior calendar year. For example, the 2013 update is based on historical data through the second quarter 2012, prior to MFP adjustment.

As shown in Table 20, the projection of the proposed revised 2006-based MEI for the CY 2014 PFS proposed rule is an increase of 0.7 percent, 0.1 percentage point lower than the projected increase using the current 2006-based MEI. In the CY 2014 PFS final rule with comment period, we will incorporate historical data through the second quarter of 2013, and therefore, the current estimated increase of 0.7 percent for 2014 may differ in the final rule.

TABLE 20—PROJECTED ANNUAL PERCENT CHANGE IN THE CY 2014 PROPOSED REVISED 2006-BASED MEI AND THE CURRENT 2006-BASED MEI *

Update year	Proposed revised 2006-based MEI	Current 2006-based MEI
CY 2014	0.7	0.8

* Based on the 2nd quarter 2013 forecast from IHS Global Insight, with historical data through the 1st quarter 2013.

For the productivity adjustment, the 10-year moving average percent change adjustment for CY 2014 is 0.9 percent, which is based on the most historical data available from BLS at the time of the proposed rule. If more recent historical data of MFP is available at the time of the final rule, we will incorporate it into the final MEI update.

TABLE 21—FORECASTED ANNUAL PERCENT CHANGE IN THE PROPOSED REVISED MEI FOR CY 2014

[All Categories]

Revised cost category	Revised price proxy	Revised cost weight (percent)	CY14 update (percent)
MEI		100.000	0.7
MFP	*10-yr moving average of* Private Nonfarm Business Multifactor Productivity.	N/A	0.9
MEI without productivity adjustment		100.000	1.6

TABLE 21—FORECASTED ANNUAL PERCENT CHANGE IN THE PROPOSED REVISED MEI FOR CY 2014—Continued

[All Categories]

Revised cost category	Revised price proxy	Revised cost weight (percent)	CY14 update (percent)
Physician Compensation		50.866	2.0
Wages and Salaries	ECI—Wages and salaries—Professional and Related (private).	43.641	1.9
Benefits	ECI—Benefits—Professional and Related (private)	7.225	2.2
Practice Expense		49.134	1.3
Non-physician compensation		16.553	1.7
Non-physician wages		11.885	1.7
Non-health, non-physician wages		7.249	1.8
Professional & Related	ECI—Wages And Salaries—Professional and Related (Private).	0.800	1.9
Management	ECI—Wages And Salaries—Managers & Administrators (Private).	1.529	1.7
Clerical	ECI—Wages And Salaries—Admin Support incl Clerical (Private).	4.720	1.8
Services	ECI—Wages And Salaries—Service Occupations (Private).	0.200	1.5
Health related, non-physician wages	ECI—Wages and Salaries—Hospital (civilian)	4.636	1.5
Non-physician benefits	Composite Benefit Index	4.668	1.7
Other Practice Expense		32.581	1.1
Utilities	CPI Fuels and Utilities	1.266	0.7
Miscellaneous Office Expenses		2.478	0.3
Chemicals	Other Basic Organic Chemical Manufacturing PPI325190.	0.723	−1.2
Paper	PPI for converted paper	0.656	1.1
Rubber & Plastics	PPI for rubber and plastics	0.598	0.3
All other products	CPI—All Items Less Food And Energy	0.500	1.9
Telephone	CPI for Telephone	1.501	0.1
Postage	CPI for Postage	0.898	4.9
All Other Professional Services		8.095	1.7
Professional, Scientific, and Tech. Svcs	ECI—Compensation: Prof. scientific, tech	2.592	1.7
Administrative and support & waste	ECI—Compensation Administrative	3.052	1.8
All Other Services	ECI Compensation: Services Occupations	2.451	1.6
Capital		10.310	0.5
Fixed	PPI for Lessors of nonresidential buildings	8.957	0.5
Moveable	PPI for Machinery and Equipment	1.353	0.8
Professional Liability Insurance	CMS—Prof. Liability. Phys. Prem. Survey	4.295	0.9
Medical Equipment	PPI—Med. Inst. & Equip	1.978	1.4
Medical supplies	Composite—PPI Surg. Appl. & CPIU Med. Supplies. (CY2006).	1.760	1.0

* Based on the 2nd quarter 2013 forecast from IHS Global Insight, with historical data through the 1st quarter 2013.

E. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, PE, and malpractice (MP)). The 89 total PFS localities are discussed in section II.E.3. of this proposed rule. While requiring that the PE and MP GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provided for a 1.0 floor for the work GPCIs, which was set to expire at the end of 2012. Section 602 of the ATRA amended the statute to extend the 1.0 floor for the work GPCIs through CY 2013 (that is, for services furnished no later than December 31, 2013).

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that ''if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made.'' Therefore, since the previous GPCI update was implemented in CY 2011 and CY 2012, we are proposing to phase in ½ of the latest GPCI adjustment in CY 2014.

We have completed a review of the GPCIs and are proposing new GPCIs, as well as a revision to the cost share weights that correspond to all three GPCIs in this proposed rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service will

deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those of the GAF.

As noted above, section 602 of the ATRA extended the 1.0 work GPCI floor only through December 31, 2013. Therefore, the proposed CY 2014 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. However, as required by sections 1848(e)(1)(G) and 1848(e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are permanent, and therefore, applicable in CY 2014. See Addenda D and E to this proposed rule for the proposed CY 2014 GPCIs and summarized GAFs available on the CMS Web site under the supporting documents section of the CY 2014 PFS proposed rule located at *http://www.cms.gov/PhysicianFeeSched/*.

2. GPCI Update

The proposed updated GPCI values were calculated by a contractor to CMS. There are three GPCIs (work, PE, and MP), and all GPCIs are calculated through comparison to a national average for each type. Additionally, each of the three GPCIs relies on its own data source(s) and methodology for calculating its value as described below. Additional information on the CY 2014 GPCI update may be found in our contractor's draft report, ''*Draft Report on the CY 2014 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule,*'' which is available on the CMS Web site. It is located under the supporting documents section of the CY 2014 PFS proposed rule located at *http://www.cms.gov/PhysicianFeeSched/*.

a. Work GPCIs

The physician work GPCIs are designed to reflect the relative costs of physician labor by Medicare PFS locality. As required by statute, the physician work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the physician work GPCIs, we use wage data for seven professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The physician work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more recent Census because the ''long form'' was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data as a replacement for the 2000 Census data. The BLS OES data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OES wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OES is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries).

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OES continues to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed in section II.E.2.b the employee wage component and purchased services component of the PE GPCI). Therefore, for the proposed CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs.

We note that the Medicare Payment Advisory Commission (MedPAC) was required by section 3004 of the MCTRJCA to submit a report to the Congress by June 15, 2013 that assesses whether any adjustment under section 1848 of the Act to distinguish the difference in work effort by geographic area is appropriate and, if so, what that level should be and where it should be applied. In the report, MedPAC was required to also assess the impact of the work geographic adjustment under the Act, including the extent to which the floor on such adjustment impacts access to care. We did not have sufficient time to review this report, which was issued on June 14, 2013 for this proposed rule. We look forward to reviewing the MedPAC report and its recommendations with respect to the work GPCI.

b. Practice Expense GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. (For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085).) The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the ''equipment, supplies and other miscellaneous expense'' cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2011 and CY 2012) we used 2006 through 2008 BLS OES data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed in section II.E.2.a., because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS

OES is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the proposed CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data for purposes of calculating the employee wage component and purchased service index of the PE GPCI.

Office Rent Index Discussion

Since the inception of the PFS, we have used residential rent data (primarily the two-bedroom residential apartment rent data produced by the Department of Housing and Urban Development (HUD) at the 50th percentile) as the proxy to measure the relative cost difference in physician office rents. As discussed in the CY 2012 PFS final rule with comment period (76 FR 73084), we had concerns with the continued use of the HUD rental data because the data were not updated frequently and the Census ''long form,'' which was used to collect the necessary base year rents for the HUD Fair Market Rent (FMR) data, was discontinued in CY 2010 and would no longer be available for future updates. Therefore, we examined the suitability of using 3-year (2006–2008) American Community Survey (ACS) rental data as a proxy for physician office rents to replace the HUD data. We determined that the ACS is one of the largest nationally representative surveys of household rents in the United States conducted annually by the U.S. Census Bureau, sampling approximately 3 million addresses with a recent response rate above 97 percent, and that it reports rental information for residences at the county level. Given that the ACS rental data provided a sufficient degree of reliability, is updated annually, and was expected to be available for future updates, we used the 2006 through 2008 ACS 3-year residential rent data as a replacement for the HUD data to create the office rent index for the CY 2012 PFS final rule with comment (76 FR 73084). For all the same reasons that we used the ACS data for the last GPCI update, we propose to use the most recent 3-year ACS residential rent data (2008 through 2010) to calculate the office rent component of the PE GPCI. We note that when responding to the ACS survey, individuals also report whether utilities are included in their rent. Thus, the cost of utilities cannot be separated from ''gross rents'' since some individuals monthly rent also covers the cost of utilities. As discussed in section II.E.2.d. we combined the cost weights for fixed capital and utilities when assigning a proposed weight to the office rent component of the PE GPCI.

For many years, we have received requests from physicians and their representatives to use commercial rent data instead of residential rent data as a proxy to measure the relative cost differences in physician office rent. Additionally, in a report entitled ''*Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy,*'' prepared for CMS under contract and released on September 28, 2011, the Institute of Medicine recommended that ''a new source of data should be developed to determine the variation in the price of commercial office rent per square foot.'' The Institute of Medicine report did not identify any new data source and did not suggest how a new source of data might be developed. Because we could not identify a reliable commercial rental data source that is available on a national basis and includes data for non-metropolitan areas, we continued to use residential rent data for the CY 2012 GPCI update.

For the CY 2014 GPCI update, we continued our efforts to identify a reliable source of commercial rent data that could be used in calculating the rent index. We could not identify a nationally representative commercial rent data source that is available in the public sector. However, we identified a proprietary commercial rent data source that has potential for use in calculating the office rent indices in future years. To that end, we are attempting to negotiate an agreement with the proprietor to use the data for purposes of calculating the office rent component of the PE GPCI.

One of the challenges of using a proprietary data source is our ability to make information available to the public. When using government data, we are able to release all data for public consideration. However, when using a proprietary data source, it is likely that restrictions will be imposed on its use and our ability to disclose data. In such a situation, those wishing to replicate our calculations based on detailed data would also need to purchase the underlying proprietary data. We also believe that, generally speaking, a proprietary ''for profit'' data source is more susceptible to periodic changes in the criteria used for data collection, including possible changes in the data collected, the frequency at which the data is updated, changes in ownership, and the potential for termination of the survey vehicle entirely as changes are made to address economic pressures or opportunities. As such, we cannot predict that a given proprietary data source will be available in the format needed to develop office rent indices in the future. Since we have not identified a nationally representative commercial rent data source that is available in the public sector, we believe it would be necessary to use a proprietary data source for commercial office rent data. That is, in the absence of using a proprietary data source, it is unlikely that we would be able to use commercial rent data to calculate the office rent index component of the PE GPCI. Therefore, we request comments on the potential future use of a proprietary commercial rent data source as well as whether there is a source for these data that is not proprietary.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature claims-made policies (policies for claims made rather than services furnished during the policy term). For the CY 2011 GPCI update (sixth update) we used 2006 and 2007 malpractice premium data (75 FR 73256). The proposed CY 2014 MP GPCI update reflects 2011 and 2012 premium data.

Additionally, for the past several GPCI updates, we were not able to collect MP premium data from insurer rate filings for the Puerto Rico payment locality. For the CY 2014 (seventh) GPCI update, we worked directly with the Puerto Rico Insurance Commissioner and Institute of Statistics to obtain data on MP insurance premiums that were used to calculate an updated MP GPCI for Puerto Rico. Using updated MP premium data would result in a 17 percent increase in MP GPCI for the Puerto Rico payment locality under the proposed fully phased-in seventh GPCI update, which would be effective CY 2015.

d. GPCI Cost Share Weights

To determine the cost share weights for the proposed CY 2014 GPCIs, we used the weights we propose to use for the CY 2014 value for the revised 2006-based Medicare Economic Index (MEI) as discussed in section II.D. of this proposed rule. As discussed in detail in that section, the MEI was rebased and revised in the CY 2011 PFS final rule with comment period (75 FR 73262 through 73277) to reflect the weighted-average annual price change for various inputs needed to provide physicians' services. We have historically updated the GPCI cost share weights to make them consistent with the most recent

update to the MEI, and propose to do so again for CY 2014. We would note that consistent with this approach in the CY 2011 proposed rule, the last time the MEI was revised, we proposed to update the GPCI cost share weights to reflect these revisions to the MEI. However, in response to public comments we did not finalize the proposal in the CY 2011 PFS final rule with comment period (75 FR 73258 and 73260), so that we could explore public comments received suggesting the reallocation of labor related costs from the medical equipment, supplies and miscellaneous component to the employee compensation component and comments received on the cost share weight for the rent index of the PE GPCI as well as to continue our analysis of the cost share weights attributed to the PE GPCIs as required by section 1848(e)(1)(H)(iv) of the Act.

In the CY 2012 PFS final rule (76 FR 73085 through 73086) we addressed commenter concerns regarding the inclusion of the cost share weight assigned to utilities within the office rent component of the PE GPCI and to geographically adjust wage related industries contained within the medical equipment, supplies and miscellaneous component of the PE GPCI. As a result, to accurately capture the utility measurement present in the ACS two bedroom gross rent data, the cost share weight for utilities was combined with the fixed capital portion to form the office rent index. Additionally, we developed a purchased service index to geographically adjust the labor-related components of the ''All Other Services'' and ''Other Professional Expenses'' categories of the 2006-based MEI market basket. Upon completing our analysis of the GPCI cost share weights (as required by the Act) and addressing commenters' concerns regarding the office rent and labor related industries previously contained in the medical equipment, supplies and other miscellaneous components of the PE GCPI, we updated the GPCI cost share weights consistent with the weights established in the 2006-based MEI in the CY 2012 PFS final rule (76 FR 73086).

The proposed revised 2006-based MEI cost share weights reflect our actuaries' best estimate of the weights associated with each of the various inputs needed to provide physicians' services. Use of the current MEI cost share weights also provides consistency across the PFS in the use of this data. Given that we have addressed previous commenters concerns about the allocation of labor related costs (as discussed earlier in this section) and that we have completed our analysis of the GPCI cost share weights (as required by the Act) we believe it is appropriate to propose to adopt the weights we are proposing to use for the revised 2006-based MEI as the GPCI cost share weights for CY 2014.

As a result, the cost share weight for the work GPCI (as a percentage of the total) in this proposal is changed from 48.266 percent to 50.866 percent, and the cost share weight for the PE GPCI is revised from 47.439 percent to 44.839 percent with a change in the employee compensation component from 19.153 to 16.553 percentage points. The cost share weights for the office rent component (10.223 percent), purchased services component (8.095 percent), and the medical equipment, supplies, and other miscellaneous expenses component (9.968 percent) of the PE GPCI and the cost share weight for the MP GPCI (4.295 percent) remains unchanged. A discussion of the specific MEI cost centers and the respective weights used to calculate each GPCI component (and subcomponent) is provided below.

(1) Work GPCIs

We propose to adopt the proposed revised weight of 50.866 for the physician compensation cost category as the proposed work GPCI cost share weight.

(2) Practice Expense GPCIs

For the cost share weight for the PE GPCIs, we used the revised 2006-based MEI proposed weight for the PE category of 49.134 percent minus the PLI category weight of 4.295 percent (because the relative costs differences in malpractice expenses are measured by its own GPCI). Therefore, the proposed cost share weight for the PE GPCIs is 44.839 percent.

(a) Employee Compensation

For the employee compensation portion of the PE GPCIs, we used the proposed non-physician employee compensation category weight of 16.553 percent reflected in the revised 2006-based MEI.

(b) Office Rent

We set the PE GPCI office rent portion at 10.223 percent which includes the proposed revised 2006-based MEI cost weights for fixed capital (reflecting the expenses for rent, depreciation on medical buildings and mortgage interest) and utilities. As discussed previously in this section, we propose to use 2008–2010 ACS rental data as the proxy for physician office rent. As mentioned previously, these data represent a gross rent amount and include data on utility expenditures. Since it is not possible to separate the utilities component of rent for all ACS survey respondents, we combined these two components to calculate office rent values that were used to calculate the office rent index component of the proposed PE GPCI. For purposes of consistency, we combined those two cost categories when assigning a proposed weight to the office rent component.

(c) Purchased Services

As discussed in section II.D. of this proposed rule, to be consistent with the purchased services index, we are proposing to combine the current MEI cost share weights for ''All Other Services'' and ''Other Professional Expenses'' into a component called ''All Other Professional Services.'' The proposed weight for ''All Other Professional Services'' is 8.095. As noted in the CY 2012 PFS final rule with comment period (76 FR 73084), we only adjust for locality cost differences of the labor-related share of the purchased services index. We determined that only 5.011 percentage points of the total 8.095 proposed weight are labor-related and, thus, would be adjusted for locality cost differences (5.011 adjusted purchased service + 3.084 non-adjusted purchased services = 8.095 total cost share weight). Therefore, only 62 percent (5.011/8.095) of the purchased service index is adjusted for geographic cost differences while the remaining 38 percent (3.084/8.095) of the purchased service index is not adjusted for geographic variation.

(d) Equipment, Supplies, and Other Miscellaneous Expenses

To calculate the medical equipment, supplies, and other miscellaneous expenses component, we removed PLI (4.295 percentage points), non-physician employee compensation (16.553 percentage points), fixed capital/utilities (10.223 percentage points), and purchased services (8.095 percentage points) from the total proposed PE category weight (44.839 percent). Therefore, the proposed cost share weight for the medical equipment, supplies, and other miscellaneous expenses component is 9.968 percent (44.839 − (4.295 + 16.553 + 10.223 + 8.095) = 9.968). As explained above, because we believe there is a national market for these items, costs that fall within this component of the PE GPCI are not adjusted for geographic variation.

(3) Malpractice GPCIs

We propose to use the PLI weight of 4.295 percent for the MP GPCI cost

share weight. The proposed GPCI cost share weights for CY 2014 are displayed in Table 22.

TABLE 22—PROPOSED COST SHARE WEIGHTS FOR CY 2014 GPCI UPDATE

Expense category	Current cost share weight (percent)	Proposed CY 2014 cost share weight (percent)
Work	48.266	50.866
Practice Expense	47.439	44.839
—Employee Compensation	19.153	16.553
—Office Rent	10.223	10.223
—Purchased Services	8.095	8.095
—Equipment, Supplies, Other	9.968	9.968
Malpractice Insurance	4.295	4.295
Total	100.000	100.000

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier States effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in States determined to be frontier States. In general, a frontier state is one in which at least 50 percent of the counties are ''frontier counties,'' which are those that have a population per square mile of less than 6. For more information on the criteria used to define a frontier state, we refer readers to the FY 2011 Inpatient Prospective Payment System final rule (75 FR 50160 through 50161). There are no changes in the States identified as ''Frontier States'' for the CY 2014 proposed rule. The qualifying States are reflected in Table 23. In accordance with statute, we will apply a 1.0 PE GPCI floor for these States in CY 2014.

TABLE 23—FRONTIER STATES UNDER SECTION 1848(E)(1)(I) OF THE ACT

[As added by section 10324(c) of the Affordable Care Act]

State	Total counties	Frontier counties	Percent frontier counties (relative to counties in the State) (percent)
Montana	56	45	80
Wyoming	23	17	74
North Dakota	53	36	68
Nevada	17	11	65
South Dakota	66	34	52

f. Proposed GPCI Update

As explained above in the background section, the periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The proposed CY 2014 updated GPCIs for the first and second year of the 2-year transition, along with the GAFs, are displayed in Addenda D and E to this proposed rule available on the CMS Web site under the supporting documents section of the CY 2014 PFS proposed rule Web page at *http://www.cms.gov/PhysicianFeeSched/*.

3. Payment Locality Discussion

a. Background

The current PFS locality structure was developed and implemented in 1997. There are currently 89 total PFS localities; 34 localities are statewide areas (that is, only one locality for the entire state). There are 52 localities in the other 16 states, with 10 states having 2 localities, 2 states having 3 localities, 1 state having 4 localities, and 3 states having 5 or more localities. The District of Columbia, Maryland, and Virginia suburbs, Puerto Rico, and the Virgin Islands are additional localities that make up the remainder of the total of 89 localities. The development of the current locality structure is described in detail in the CY 1997 PFS proposed rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494).

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments were based on the charging patterns of physicians. This resulted in large differences in payment for physicians' services among types of services, geographic payment areas, and physician specialties. Recognizing this, the Congress replaced the reasonable charge system with the Medicare PFS in the Omnibus Budget Reconciliation Act (OBRA) of 1989, and the PFS went into effect January 1, 1992. Payments under the PFS are based on the relative resources involved with furnishing services, and are adjusted to account for geographic variations in resource costs as measured by the GPCIs.

Payment localities originally were established under the reasonable charge system by local Medicare carriers based on their knowledge of local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. Shortly after the PFS took effect, CMS undertook a study in 1994 that culminated in a comprehensive locality revision that was implemented in 1997 (61 FR 59494).

The revised locality structure reduced the number of localities from 210 to the current 89, and the number of statewide localities increased from 22 to 34. The revised localities were based on locality resource cost differences as reflected by the GPCIs. For a full discussion of the methodology, see the CY 1997 PFS final rule with comment period (61 FR 59494). The current 89 fee schedule areas are defined alternatively by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality

configuration is used to calculate the GPCIs that are in turn used to calculate payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), we require that changes to the PFS locality structure be done in a budget neutral manner within a state. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. In recent years, we have also considered more comprehensive changes to locality configuration. In 2008, we issued a draft comprehensive report detailing four different locality configuration options (*www.cms.gov/physicianfeesched/downloads/ReviewOfAltGPCIs.pdf*). The alternative locality configurations in the report are described below.

- *Option 1: CMS Core-Based Statistical Area (CBSA) Payment Locality Configuration:* CBSAs are a combination of Office of Management and Budget (OMB's) Metropolitan Statistical Areas (MSAs) and Micropolitan Statistical Areas. Under this option, MSAs would be considered as urban CBSAs. Micropolitan Statistical Areas (as defined by OMB) and rural areas would be considered as non-urban (rest of state) CBSAs. This approach would be consistent with the areas used in the Inpatient Prospective Payment System (IPPS) pre-reclassification wage index, which is the hospital wage index for a geographic area (CBSA or non-CBSA) calculated from submitted hospital cost report data before statutory adjustments reconfigure, or ''reclassify'' a hospital to an area other than its geographic location, to adjust payments for differences in local resource costs in other Medicare payment systems. Based on data used in the 2008 locality report, this option would increase the number of PFS localities from 89 to 439.
- *Option 2: Separate High-Cost Counties from Existing Localities (Separate Counties):* Under this approach, higher cost counties are removed from their existing locality structure, and they would each be placed into their own locality. This option would increase the number of PFS localities from 89 to 214, using a 5 percent GAF differential to separate high-cost counties.
- *Option 3: Separate MSAs from Statewide Localities (Separate MSAs):* This option begins with statewide localities and creates separate localities for higher cost MSAs (rather than removing higher cost counties from their existing locality as described in Option 2). This option would increase the number of PFS localities from 89 to 130, using a 5 percent GAF differential to separate high-cost MSAs.
- *Option 4: Group Counties Within a State Into Locality Tiers Based on Costs (Statewide Tiers):* This option creates tiers of counties (within each state) that may or may not be contiguous but share similar practice costs. This option would increase the number of PFS localities from 89 to 140, using a 5 percent GAF differential to group similar counties into statewide tiers.

For a detailed discussion of the public comments on the contractor's 2008 draft report detailing four different locality configurations, we refer readers to the CY 2010 PFS proposed rule (74 FR 33534) and subsequent final rule with comment period (74 FR 61757). There was no public consensus on the options, although a number of commenters expressed support for Option 3 (separate MSAs from statewide localities) because the commenters believed this alternative would improve payment accuracy and could mitigate potential reductions to rural areas compared to Option 1 (CMS CBSAs).

In response to some public comments regarding the third of the four locality options, we had our contractor conduct an analysis of the impacts that would result from the application of Option 3. Those results were displayed in the final locality report released in 2011. The final report, entitled ''*Review of Alternative GPCI Payment Locality Structures—Final Report,*'' may be accessed directly from the CMS Web site at *www.cms.gov/PhysicianFee Sched/downloads/Alt_GPCI_Payment_Locality_Structures_Review.pdf.*

Moreover, at our request, the Institute of Medicine conducted a comprehensive empirical study of the Medicare GAFs established under sections 1848(e) (PFS GPCI) and 1886(d)(3)(E) (IPPS hospital wage index) of the Act. These adjustments are designed to ensure Medicare payments reflect differences in input costs across geographic areas. The first of the Institute of Medicine's two reports entitled, ''*Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy*'' recommended that the same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor. Further, the Institute of Medicine recommended that MSAs and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets.

Under the Institute of Medicine's recommendations, MSAs would be considered as urban CBSAs. Micropolitan Areas (as defined by the OMB) and rural areas would be considered as non-urban (rest of State) CBSAs. This approach would be consistent with the areas used in the IPPS pre-reclassification wage index to make geographic payment adjustments in other Medicare payment systems. For more information on the Institute of Medicine's recommendations on the PFS locality structure, see the CY 2013 PFS final rule with comment period (77 FR 68949). We also provided our technical analyses of the Institute of Medicine Phase I recommendations in a report released on the PFS Web site at *www.cms.gov/PhysicianFeeSched.*

Additionally, the Phase I report can be accessed on the Institute of Medicine's Web site at *http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.*

b. Institute of Medicine Phase II Report Discussion

The Institute of Medicine's second report, entitled ''*Geographic Adjustment in Medicare Payment—Phase II: Implications for Access, Quality, and Efficiency*'' was released July 17, 2012 and can be accessed on the Institute of Medicine's Web site at *http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.*

The Phase II report evaluated the effects of geographic adjustment factors (hospital wage index and GPCIs) on the distribution of the health care workforce, quality of care, population health, and the ability to provide efficient, high value care. The Institute of Medicine's Phase II report also included an analysis of the impacts of implementing its recommendations for accuracy in geographic adjustments which include a CBSA-based locality structure under the PFS. The Institute of Medicine analysis found that adopting a CBSA-based locality structure under the PFS creates large changes in county GAF values; for example, approximately half of all US counties would experience a payment reduction. The Institute of Medicine also found that GPCIs calculated under a CBSA-based locality structure would result in lower GAFs in rural areas (relative to the national average) because the GPCI values for rural areas would no longer include metropolitan practice costs within the current ''rest-of-state'' or ''statewide'' localities.

(1) Institute of Medicine Phase II Report Recommendations

The Institute of Medicine developed recommendations for improving access to and quality of medical care. The

recommendations included in the Institute of Medicine's Phase II report are summarized as follows:

- *Recommendation 1:* The Medicare program should develop and apply policies that promote access to primary care services in geographic areas where Medicare beneficiaries experience persistent access problems.
- *Recommendation 2:* The Medicare program should pay for services that improve access to primary and specialty care for beneficiaries in medically underserved urban and rural areas, particularly telehealth technologies.
- *Recommendation 3:* To promote access to appropriate and efficient primary care services, the Medicare program should support policies that would allow all qualified practitioners to practice to the full extent of their educational preparation.
- *Recommendation 4:* The Medicare program should reexamine its policies that provide location-based adjustments for specific groups of hospitals, and modify or discontinue them based on their effectiveness in ensuring adequate access to appropriate care.
- *Recommendation 5:* Congress should fund an independent ongoing entity, such as the National Health Care Workforce Commission, to support data collection, research, evaluations, and strategy development, and make actionable recommendations about workforce distribution, supply, and scope of practice.
- *Recommendation 6:* Federal support should facilitate independent external evaluations of ongoing workforce programs intended to provide access to adequate health services for underserved populations and Medicare beneficiaries. These programs include the National Health Services Corps, Title VII and VIII programs under the Public Health Service Act, and related programs intended to achieve these goals.

(2) Institute of Medicine Phase II Report Conclusions

The Institute of Medicine committee concluded that geographic payment adjustments under the PFS are not a strong determinant of access problems and not an appropriate mechanism for improving the distribution of the healthcare workforce, quality of care, population health, and the ability to provide efficient, high value care. Specifically, the Institute of Medicine committee stated ''that there are wide discrepancies in access to and quality of care across geographic areas particularly for racial and ethnic minorities. However, the variations do not appear to be strongly related to differences in or potential changes to fee for service payment'' (Page. 6). The committee also concluded ''that Medicare beneficiaries in some geographic pockets face persistent access and quality problems, and many of these pockets are in medically underserved rural and inner-city areas. However, geographic adjustment of Medicare payment is not an appropriate approach for addressing problems in the supply and distribution of the health care workforce. The geographic variations in the distribution of physicians, nurses and physician assistants, and local shortages that create access problems for beneficiaries should be addressed through other means'' (Page. 7). Moreover, the committee concluded that ''geographic [payment] adjustment is not an appropriate tool for achieving policy goals such as improving quality of expanding the pool of providers available to see Medicare beneficiaries'' (Page. 9).

(3) CMS Summary Response to Institute of Medicine Phase II Report

The Institute of Medicine's Phase II report recommendations are broad in scope, do not propose specific recommendations for making changes to the GPCIs or PFS locality structure, or are beyond the statutory authority of CMS.

We agree with the Institute of Medicine's assessment that many counties would experience a payment reduction and that large payment shifts would occur as a result of implementing a CBSA-based locality configuration under the PFS. Based on our contractor's analysis, there would be significant redistributive impacts if we were to implement a policy that would reconfigure the PFS localities based on the Institute of Medicine's CBSA-based locality recommendation. Many rural areas would see substantial decreases in their corresponding GAF and GPCI values as higher cost counties are removed from current ''rest of state'' payment areas. Conversely, many urban areas, especially those areas that are currently designated as ''rest of state'' but are located within higher cost MSAs, would experience increases in their applicable GPCIs and GAFs. That is, given that urban and rural areas would no longer be grouped together (for example, as in the current 34 statewide localities), many rural areas would see a reduction in payment under a CBSA-based locality configuration.

As noted earlier in this section, we are assessing a variety of approaches to changing the locality structure under the PFS and will continue to study options for revising the locality structure. However, to fully assess the implications of proposing a nationwide locality reconfiguration under the PFS, we must also assess and analyze the operational changes necessary to implement a revised locality structure. Given that all options under consideration (including the Institute of Medicine's CBSA-based approach) would expand the number of current localities and result in payment reductions to primarily rural areas, presumably any nationwide locality reconfiguration could potentially be transitioned over a number of years (to phase-in the impact of payment reductions gradually, from year to year, instead of all at once). As such, transitioning from the current locality structure to a nationwide reconfigured locality structure would present operational and administrative challenges that need to be identified and addressed. Therefore, we have begun to assess the broad operational changes that would be involved in implementing a nationwide locality reconfiguration under the PFS. Accordingly, we believe that it would be premature to make any statements about potential changes we would consider making to the PFS localities at this time. Any changes to PFS fee schedule areas would be made through future notice and comment rulemaking.

In the event that we develop a specific proposal for changing the locality configuration during future rulemaking, we would provide detailed analysis on the impact of the changes for physicians in each county. We would also provide opportunities for public input.

F. Medicare Telehealth Services for the Physician Fee Schedule

1. Billing and Payment for Telehealth Services

a. History

Prior to January 1, 1999, Medicare coverage for services delivered via a telecommunications system was limited to services that did not require a face-to-face encounter under the traditional model of medical care. Examples of these services included interpretation of an x-ray, electroencephalogram tracing, and cardiac pacemaker analysis.

Section 4206 of the BBA provided for coverage of, and payment for, consultation services delivered via a telecommunications system to Medicare beneficiaries residing in rural health professional shortage areas (HPSAs) as defined by the Public Health Service Act. Additionally, the BBA required that a Medicare practitioner (telepresenter) be with the patient at the time of a teleconsultation. Further, the BBA

specified that payment for a teleconsultation had to be shared between the consulting practitioner and the referring practitioner and could not exceed the fee schedule payment that would have been made to the consultant for the service furnished. The BBA prohibited payment for any telephone line charges or facility fees associated with the teleconsultation. We implemented this provision in the CY 1999 PFS final rule with comment period (63 FR 58814).

Effective October 1, 2001, section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement Protection Act of 2000 (BIPA) (Pub. L. 106–554) added section 1834(m) to the Act, which significantly expanded Medicare telehealth services. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when delivered via a telecommunications system. We first implemented this provision in the CY 2002 PFS final rule with comment period (66 FR 55246). Section 1834(m)(4)(F)(ii) of the Act required the Secretary to establish a process that provides for annual updates to the list of Medicare telehealth services. We established this process in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified in regulations at § 410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined as, ''multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.'' An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act allows the use of asynchronous ''store-and-forward'' technology when the originating site is a federal telemedicine demonstration program in Alaska or Hawaii. As specified in regulations at § 410.78(a)(1), store-and-forward means the asynchronous transmission of medical information from an originating site to be reviewed at a later time by the practitioner at the distant site.

Medicare telehealth services may be furnished to an eligible telehealth individual notwithstanding the fact that the practitioner furnishing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual means an individual enrolled under Part B who receives a telehealth service furnished at an originating site. Under the BIPA, originating sites were limited under section 1834(m)(3)(C) of the Act to specified medical facilities located in specific geographic areas. The initial list of telehealth originating sites included the office of a practitioner, a critical access hospital (CAH), a rural health clinic (RHC), a federally qualified health center (FQHC) and a hospital (as defined in section 1861(e) of the Act). More recently, section 149 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) expanded the list of telehealth originating sites to include a hospital-based renal dialysis center, a skilled nursing facility (SNF), and a community mental health center (CMHC). To serve as a telehealth originating site, a site must also be located in an area designated as a rural HPSA, in a county that is not in a metropolitan statistical area (MSA), or must be an entity that participates in a federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary as of December 31, 2000. Finally, section 1834(m) of the Act does not require the eligible telehealth individual to be with a telepresenter at the originating site.

b. Current Telehealth Billing and Payment Policies

As noted previously, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in a qualifying originating site. An originating site is defined as one of the specified sites where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system. The originating sites authorized by the statute are as follows:

- Offices of a physician or practitioner;
- Hospitals;
- CAHs;
- RHCs;
- FQHCs;
- Hospital-Based or Critical Access Hospital-Based Renal Dialysis Centers (including Satellites);
- SNFs;
- CMHCs.

Currently approved Medicare telehealth services include the following:

- Initial inpatient consultations;
- Follow-up inpatient consultations;
- Office or other outpatient visits;
- Individual psychotherapy;
- Pharmacologic management;
- Psychiatric diagnostic interview examination;
- End-stage renal disease (ESRD) related services;
- Individual and group medical nutrition therapy (MNT);
- Neurobehavioral status exam;
- Individual and group health and behavior assessment and intervention (HBAI);
- Subsequent hospital care;
- Subsequent nursing facility care;
- Individual and group kidney disease education (KDE);
- Individual and group diabetes self-management training (DSMT);
- Smoking cessation services;
- Alcohol and/or substance abuse and brief intervention services;
- Screening and behavioral counseling interventions in primary care to reduce alcohol misuse;
- Screening for depression in adults;
- Screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs;
- Intensive behavioral therapy for cardiovascular disease; and
- Behavioral counseling for obesity.

In general, the practitioner at the distant site may be any of the following, provided that the practitioner is licensed under state law to furnish the service via a telecommunications system:

- Physician;
- Physician assistant (PA);
- Nurse practitioner (NP);
- Clinical nurse specialist (CNS);
- Nurse-midwife;
- Clinical psychologist;
- Clinical social worker;
- Registered dietitian or nutrition professional.

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare contractors that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system. Distant site practitioners must submit the appropriate HCPCS procedure code for a covered professional telehealth service, appended with the –GT (via interactive audio and video telecommunications system) or –GQ (via asynchronous telecommunications system) modifier. By reporting the –GT or –GQ modifier with a covered

telehealth procedure code, the distant site practitioner certifies that the beneficiary was present at a telehealth originating site when the telehealth service was furnished. The usual Medicare deductible and coinsurance policies apply to the telehealth services reported by distant site practitioners.

Section 1834(m)(2)(B) of the Act provides for payment of a facility fee to the originating site. To be paid the originating site facility fee, the provider or supplier where the eligible telehealth individual is located must submit a claim with HCPCS code Q3014 (telehealth originating site facility fee), and the provider or supplier is paid according to the applicable payment methodology for that facility or location. The usual Medicare deductible and coinsurance policies apply to HCPCS code Q3014. By submitting HCPCS code Q3014, the originating site certifies that it is located in either a rural HPSA or non-MSA county or is an entity that participates in a federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary as of December 31, 2000 as specified in section 1834(m)(4)(C)(i)(III) of the Act.

As previously described, certain professional services that are commonly furnished remotely using telecommunications technology, but that do not require the patient to be present in-person with the practitioner when they are furnished, are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in-person at the medical facility furnishing care to the patient. Such services typically involve circumstances where a practitioner is able to visualize some aspect of the patient's condition without the patient being present and without the interposition of a third person's judgment. Visualization by the practitioner can be possible by means of x-rays, electrocardiogram or electroencephalogram tracings, tissue samples, etc. For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted via telephone (that is, electronically, rather than by means of a verbal description) is a covered physician's service. These remote services are not Medicare telehealth services as defined under section 1834(m) of the Act. Rather, these remote services that utilize telecommunications technology are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way (that is, without the –GT or –GQ modifier appended).

c. Geographic Criteria for Originating Site Eligibility

Section 1834(m)(4)(C)(i)(I)–(III) of the Act specifies three criteria for the location of eligible telehealth originating sites. One of these is for entities participating in federal telemedicine demonstration projects as of December 31, 2000, and the other two are geographic. One of the geographic criteria is that the site is located in a county that is not in an MSA and the other is that the site is located in an area that is designated as a rural HPSA under section 332(a)(1)(A) of the Public Health Service Act (PHSA) (42 U.S.C. 254e(a)(1)(A)). Section 332(a)(1)(A) of the PHSA provides for the designation of various types of HPSAs, but does not provide for ''rural'' HPSAs. In the absence of guidance in the PHSA, CMS has in the past interpreted the term ''rural'' under section 1834(m)(4)(C)(i)(I) to mean an area that is not located in an MSA. As such, the current geographic criteria for telehealth originating sites limits eligible sites to those that are not in an MSA.

To determine rural designations with more precision, HHS and CMS have sometimes used methods that do not rely solely on MSA designations. For example, the Office of Rural Health Policy (ORHP) uses the Rural Urban Commuting Areas (RUCAs) to determine rural areas within MSAs. RUCAs are a census tract-based classification scheme that utilizes the standard Bureau of Census Urbanized Area and Urban Cluster definitions in combination with work commuting information to characterize all of the nation's census tracts regarding their rural and urban status and relationships. They were developed under a collaborative project between ORHP, the U.S. Department of Agriculture's Economic Research Service (ERS), and the WWAMI Rural Health Research Center (RHRC). A more comprehensive description is available at the USDA ERS Web site at: *www.ers.usda.gov/data-products/rural-urban-commuting-area-codes/documentation.aspx#.UcsKfZwzZKE*. The RUCA classification scheme contains 10 primary and 30 secondary codes. The primary code numbers (1 through 10) refer to the primary, or single largest, commuting share. Census tracts with RUCA codes of 4 through 10 refer to areas with a primary commuting share outside of a metropolitan area. In addition to counties that are not in an MSA, ORHP considers some census tracts in MSA counties to be rural. Specifically, census tracts with RUCA codes 4 through 10 are considered to be rural, as well as census tracts with RUCA codes 2 and 3 that are also at least 400 square miles and have a population density of less than 35 people per square mile.

We are proposing to modify our regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by ORHP. We believe that defining ''rural'' to include geographic areas located in rural census tracts within MSAs would allow for the appropriate inclusion of additional HPSAs as areas for telehealth originating sites. We also believe that adopting the more precise definition of ''rural'' for this purpose would expand access to health care services for Medicare beneficiaries located in rural areas.

We are also proposing to change our policy so that geographic eligibility for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies. Absent this proposed change, the status of a geographic area's eligibility for telehealth originating site payment is effective at the same time as the effective date for changes in designations that are made outside of CMS. This proposed change would reduce the likelihood that mid-year changes to geographic designations would result in sudden disruptions to beneficiaries' access to services, unexpected changes in eligibility for established telehealth originating sites and avoid the operational difficulties associated with administering with mid-year Medicare telehealth payment changes. We are proposing to establish geographic eligibility for Medicare telehealth originating sites for each calendar year based upon the status of the area as of December 31st of the prior calendar year. Accordingly, we are proposing to revise our regulations at § 410.78(b)(4) to conform with both of these proposed policies.

2. Adding Services to the List of Medicare Telehealth Services

As noted previously, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. We assign any request to make additions to the list of telehealth services to one of

two categories. In the November 28, 2011 **Federal Register** (76 FR 73102), we finalized revisions to criteria that we use to review requests in the second category. The two categories are:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. In reviewing these requests, we look for evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

Since establishing the process to add or remove services from the list of approved telehealth services, we have added the following to the list of Medicare telehealth services: Individual and group HBAI services; psychiatric diagnostic interview examination; ESRD services with 2 to 3 visits per month and 4 or more visits per month (although we require at least 1 visit a month to be furnished in-person by a physician, CNS, NP, or PA to examine the vascular access site); individual and group MNT; neurobehavioral status exam; initial and follow-up inpatient telehealth consultations for beneficiaries in hospitals and skilled nursing facilities (SNFs); subsequent hospital care (with the limitation of one telehealth visit every 3 days); subsequent nursing facility care (with the limitation of one telehealth visit every 30 days); individual and group KDE; and individual and group DSMT (with a minimum of 1 hour of in-person instruction to ensure effective injection training), smoking cessation services; alcohol and/or substance abuse and brief intervention services; screening and behavioral counseling interventions in primary care to reduce alcohol misuse; screening for depression in adults; screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs; intensive behavioral therapy for cardiovascular disease; and behavioral counseling for obesity.

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, requests submitted before the end of CY 2013 will be considered for the CY 2015 proposed rule. Each request for adding a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requestors should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at *www.cms.gov/telehealth/*.

3. Submitted Requests and Other Additions to the List of Telehealth Services for CY 2014

We received a request in CY 2012 to add online assessment and E/M services as Medicare telehealth services effective for CY 2014. The following presents a discussion of this request, and our proposals for additions to the CY 2014 telehealth list.

a. Submitted Requests

The American Telemedicine Association (ATA) submitted a request to add CPT codes 98969 (Online assessment and management service provided by a qualified nonphysician health care professional to an established patient, guardian, or health care provider not originating from a related assessment and management service provided within the previous 7 days, using the Internet or similar electronic communications network) and 99444 (Online evaluation and management service provided by a physician to an established patient, guardian, or health care provider not originating from a related E/M service provided within the previous 7 days, using the Internet or similar electronic communications network) to the list of Medicare telehealth services.

As we explained in the CY 2008 PFS final rule with comment period (72 FR 66371), we assigned a status indicator of ''N'' (Non-covered service) to these services because: (1) These services are non-face-to-face; and (2) the code descriptor includes language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (for example, a guardian). Under section 1834(m)(2)(A) of the Act, Medicare pays the physician or practitioner furnishing a telehealth service an amount equal to the amount that would have been paid if the service was furnished without the use of a telecommunications system. Because CPT codes 98969 and 99444 are currently noncovered, there would be no Medicare payment if these services were furnished without the use of a telecommunications system. Since these codes are noncovered services for which no payment may be made under Medicare, we are not proposing to add online evaluation and management services to the list of Medicare Telehealth Services for CY 2014.

b. Other Additions

Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the

existing telehealth list with respect to the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 proposed rule (76 FR 42826), we believe that the category 1 criteria not only streamline our review process for publically requested services that fall into this category, the criteria also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

For CY 2013, CMS finalized a payment policy for new CPT code 99495 (Transitional care management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge medical decision making of at least moderate complexity during the service period face-to-face visit, within 14 calendar days of discharge) and CPT code 99496 (Transitional care management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge medical decision making of high complexity during the service period face-to-face visit, within 7 calendar days of discharge). These services are for a patient whose medical and/or psychosocial problems require moderate or high complexity medical decision making during transitions in care from an inpatient hospital setting (including acute hospital, rehabilitation hospital, long-term acute care hospital), partial hospitalization, observation status in a hospital, or skilled nursing facility/nursing facility, to the patient's community setting (home, domiciliary, rest home, or assisted living). Transitional care management is comprised of one face-to-face visit within the specified time frames following a discharge, in combination with non-face-to-face services that may be performed by the physician or other qualified health care professional and/or licensed clinical staff under his or her direction.

We believe that that the interactions between the furnishing practitioner and the beneficiary described by the required face-to-face visit component of the TCM services are sufficiently similar to services currently on the list of Medicare telehealth services for these services to be added under category 1. Specifically, we believe that the required face-to-face visit component of TCM services is similar to the office/outpatient evaluation and management visits described by CPT codes 99201–99205 and 99211–99215. We note that like certain other non-face-to-face PFS services, the other components of the TCM service are commonly furnished remotely using telecommunications technology, and do not require the patient to be present in-person with the practitioner when they are furnished. As such, we do not need to consider whether the non-face-to-face aspects of the TCM service are similar to other telehealth services. Were these components of the TCM services separately billable, they would not need to be on the telehealth list to be covered and paid in the same way as services delivered without the use of telecommunications technology. Therefore, we are proposing to add CPT codes 99495 and 99496 to the list of telehealth services for CY 2014 on a category 1 basis. Consistent with this proposal, we are also proposing to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include TCM services as Medicare telehealth services.

4. Telehealth Frequency Limitations

The ATA asked that we remove the telehealth frequency limitation for subsequent nursing facility services reported by CPT codes 99307 through 99310. Subsequent nursing facility services were added to the list of Medicare telehealth services in the CY 2011 PFS final rule (75 FR 73317 through 73318), with a limitation of one telehealth subsequent nursing facility care service every 30 days. In the CY 2011 PFS final rule (75 FR 73615) we noted that, as specified in our regulation at § 410.78(e)(2), the federally mandated periodic SNF visits required under § 483.40(c) could not be furnished through telehealth.

The ATA requested that the frequency limitation be removed due to ''recent federal telecommunications policy changes'' and newly available information from recent studies. Specifically, the ATA pointed to the Federal Communications Commission (FCC) pilot funding of a program to facilitate the creation of a nationwide broadband network dedicated to health care, connecting public and private non-profit health care providers in rural and urban locations, and a series of studies that demonstrated the value to patients of telehealth technology.

In considering this request, we began with the analysis contained in the CY 2011 proposed rule (75 FR 73318), when we proposed to add SNF subsequent care, to the list of Medicare telehealth services. We discussed our complementary commitments to ensuring that SNF residents, given their potential clinical acuity, continue to receive in-person visits as appropriate to manage their complex care and to make sure that Medicare pays only for medically reasonable and necessary care. To meet these commitments, we believed it was appropriate to limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days.

We then reviewed the publicly available information regarding both the FCC pilot program and the ATA-referenced studies in light of the previously stated commitments to assess whether these developments warrant a change in 30-day frequency limitation policy. Based on our review of the FCC demonstration project and the studies referenced in the request, we found no information regarding the relative clinical benefits of SNF subsequent care when furnished via telehealth more frequently than once every 30 days. We did note that the FCC information reflected an aim to improve access to medical specialists in urban areas for rural health care providers, and that medical specialists in urban areas can continue to use the inpatient telehealth consultation HCPCS G-codes (specifically G0406, G0407, G0408, G0425, G0426, or G0427) when reporting medically reasonable and necessary consultations furnished to SNF residents via telehealth without any frequency limitation.

We also reviewed the studies referenced by the ATA to assess whether they provided evidence that more frequent telehealth visits would appropriately serve this particular population given the potential medical acuity and complexity of patient needs. We did not find any such evidence in the studies. Three of the studies identified by the ATA were not directly relevant to SNF subsequent care services. One of these focused on using telehealth technology to treat patients with pressure ulcers after spinal cord injuries. The second focused on the usefulness of telehealth technology for patients receiving home health care services. A third study addressed the use of interactive communication technology to facilitate the coordination of care between hospital and SNF personnel on the day of hospital discharge. The ATA also mentioned a peer-reviewed presentation delivered at its annual meeting related to SNF patient care, suggesting that the presentation demonstrated that telehealth visits are better for SNF patients than in-person visits to emergency departments or, in some cases, visits to physician offices. Although we did not have access to the full presentation it does not appear to

address subsequent nursing facility services, so we do not believe this is directly relevant to the clinical benefit of SNF subsequent care furnished via telehealth. More importantly, none of these studies addresses the concerns we have expressed about the possibility that nursing facility subsequent care visits furnished too frequently through telehealth rather than in-person could compromise care for this potentially acute and complex patient population.

We remain committed to ensuring that SNF inpatients receive appropriate in-person visits and that Medicare pays only for medically reasonable and necessary care. We are not persuaded by the information submitted by the ATA that it would be beneficial or advisable to remove the frequency limitation we established for SNF subsequent care when furnished via telehealth. Because we want to ensure that nursing facility patients with complex medical conditions have appropriately frequent, medically reasonable and necessary encounters with their admitting practitioner, we continue to believe that it is appropriate for some subsequent nursing facility care services to be furnished through telehealth. At the same time, because of the potential acuity and complexity of SNF inpatients, we remain committed to ensuring that these patients continue to receive in-person, hands-on visits as appropriate to manage their care. Therefore, we are not proposing any changes to the limitations regarding SNF subsequent care services furnished via telehealth for CY 2014.

G. Therapy Caps

1. Outpatient Therapy Caps for CY 2014

Section 1833(g) of the Act applies annual, per beneficiary, limitations on expenses considered incurred for outpatient therapy services under Medicare Part B, commonly referred to as ''therapy caps.'' There is one therapy cap for outpatient occupational therapy (OT) services and another separate therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined.

Until October 1, 2012, the therapy caps applied to all outpatient therapy services except those furnished by a hospital or another entity under an arrangement with a hospital described under section 1833(a)(8)(B) of the Act. For convenience, we will refer to the exemption from the caps for services described under section 1833(a)(8)(B) of the Act as the ''outpatient hospital services exemption.'' Section 3005(b) of the MCTRJCA added section 1833(g)(6) of the Act to temporarily suspend the outpatient hospital services exemption, thereby requiring that the therapy caps apply to services described under section 1833(a)(8)(B) of the Act from October 1, 2012 to December 31, 2012 for services furnished during 2012. This broadened application of the therapy caps was extended through December 31, 2013, by section 603(a) of the ATRA. In addition, section 603(b) of the ATRA amended section 1833(g)(6) of the Act to specify that during CY 2013, for outpatient therapy services paid under section 1834(g) of the Act (those furnished by a critical access hospital (CAH)), we must count towards the therapy caps the amount that would be payable for the services under Medicare Part B if the services were paid as outpatient therapy services under section 1834(k)(1)(B) of the Act, which describes payment for outpatient therapy services furnished by hospitals and certain other entities, instead of as CAH outpatient therapy services under section 1834(g) of the Act. Payment for outpatient therapy services under section 1834(k)(1)(B) of the Act is made at 80 percent of the lesser of the actual charge for the services or the applicable fee schedule amount as defined in section 1834(k)(3) of the Act. Section 1834(k)(3) of the Act defines applicable fee schedule to mean the payment amount determined under a fee schedule established under section 1848 of the Act, which refers to the PFS, or an amount under a fee schedule for comparable services as the Secretary specifies. The PFS is required as the applicable fee schedule to be used as the payment basis under section 1834(k)(3) of the Act. Section 603(b) of the ATRA also specified that nothing in the amendments to section 1833(g)(6) of the Act ''shall be construed as changing the method of payment for outpatient therapy services under 1834(g) of the Act.''

Since CY 2011, a therapy multiple procedure payment reduction (MPPR) policy has applied to the second and subsequent ''always therapy'' services billed on the same date of service for one patient by the same practitioner or facility under the same NPI. Prior to April 1, 2013, the therapy MPPR reduced the practice expense portion of office-based services by 20 percent and reduced the practice expense portion of institutional-based services by 25 percent. As of April 1, 2013, section 633(a) of the ATRA amended sections 1848(b)(7) and 1834(k) of the Act to increase the therapy MPPR to 50 percent for all outpatient therapy services furnished in office-based and institutional settings. (For more information on the MPPR and its history, see section II.B.4 of this proposed rule.)

Sections 1833(g)(1) and (3) of the Act specify that in counting services towards the cap, ''no more than the amount specified in paragraph (2) for the year shall be considered incurred expenses.'' As noted above, section 603(b) of the ATRA amended section 1833(g)(6) of the Act to require that outpatient therapy services furnished by CAHs during CY 2013 are counted towards the therapy caps using the amount that would be paid for those services under section 1834(k)(1)(B) of the Act, which is how outpatient therapy services furnished by hospitals and certain other entities are paid. Since payment for outpatient therapy services under section 1834(k)(1)(B) of the Act is made at the PFS rate and includes any applicable therapy MPPR, the amounts for incurred expenses counted toward the caps for therapy services furnished by a CAH also reflect any applicable therapy MPPR.

We believe that this is consistent with the statutory amendments made by the ATRA. Including the therapy MPPR in calculating incurred expenses for therapy services furnished by CAHs treats CAH services consistently with services furnished in other applicable settings. Therefore, therapy services furnished by CAHs during CY 2013 count towards the therapy caps using the amount that would be payable under section 1834(k)(1)(B) of the Act, which includes an applicable MPPR. For a list of the ''always therapy'' codes subject to the therapy MPPR policy, see Addendum H of this proposed rule.

The therapy cap amounts under section 1833(g) of the Act are updated each year based on the Medicare Economic Index (MEI). Specifically, the annual caps are calculated by updating the previous year's cap by the MEI for the upcoming calendar year and rounding to the nearest $10 as specified in section 1833(g)(2)(B) of the Act. The therapy cap amounts for CY 2014 will be announced in the CY 2014 PFS final rule with comment period.

An exceptions process for the therapy caps has been in effect since January 1, 2006. Originally required by section 5107 of the Deficit Reduction Act of 2005 (DRA), which amended section 1833(g)(5) of the Act, the exceptions process for the therapy caps has been continuously extended several times through subsequent legislation (MIEA–TRHCA, MMSEA, MIPPA, the Affordable Care Act, MMEA, TPTCCA, and MCTRJCA). Last amended by section 603(a) of the ATRA, the Agency's current authority to provide an

exceptions process for therapy caps expires on December 31, 2013. After expenses incurred for the beneficiary's services for the year have exceeded the therapy cap, therapy suppliers and providers use the KX modifier on claims for services to request an exception to the therapy caps. By use of the KX modifier, the therapist is attesting that the services above the therapy cap are reasonable and necessary and that there is documentation of medical necessity for the services in the beneficiary's medical record.

Under section 1833(g)(5)(C) of the Act, added by the MCTRJCA and extended through 2013 by the ATRA, we are required to apply a manual medical review process to therapy claims when a beneficiary's incurred expenses exceed a threshold amount of $3,700. There are two separate thresholds of $3,700, just as there are two therapy caps, and incurred expenses are counted toward the thresholds in the same manner as the caps. Under the statute, the required application of the manual medical review process expires December 31, 2013. For information on the manual medical review process, go to *www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/TherapyCap.html*.

2. Proposed Application of Therapy Caps to Services Furnished by CAHs

Section 4541 of the BBA amended section 1833(g) of the Act to create the therapy caps discussed above. This BBA provision applied the therapy caps to outpatient therapy services described at section 1861(p) of the Act except for the outpatient therapy services described in section 1833(a)(8)(B) of the Act. Section 1833(a)(8)(B) of the Act refers to therapy services furnished by a hospital to an outpatient, to services furnished to a hospital inpatient who has exhausted, or is not entitled to, benefits under Part A; and to these same services when furnished by an entity under arrangements with a hospital. Payment for the services described under section 1833(a)(8)(B) of the Act is made under section 1834(k)(1)(B) of the Act.

Section 4201 of the BBA amended section 1820 of the Act to require a process for establishment of CAHs. Payment for CAH outpatient services is described under section 1834(g) of the Act.

When we proposed language to implement the BBA provision establishing therapy caps in the CY 1999 PFS proposed rule, we indicated in the preamble that the therapy caps do not apply to therapy services furnished directly or under arrangements by a hospital or CAH to an outpatient or to an inpatient who is not in a covered Part A stay (63 FR 30818, 30858). We included a similar statement in the preamble to the final rule; however, we did not include the same reference to CAHs in that sentence in the CY 1999 PFS final rule with comment period (63 FR 58814, 58865). In the CY 1999 PFS final rule with comment period, we also stated generally that the therapy caps apply only to items and services furnished by nonhospital providers and therapists (63 FR 58865). In the CY 1999 proposed rule, we proposed to include provisions at § 410.59(e)(3) and § 410.60(e)(3) to describe, respectively, the outpatient therapy services that are exempt from the statutory therapy caps for outpatient OT services, and for outpatient PT and SLP services combined. Specifically, in the CY 1999 PFS proposed rule, we proposed to add the following regulatory language for OT and for PT at §§ 410.59(e)(3) and 410.60(e)(3): ''For purposes of applying the limitation, outpatient [occupational therapy/physical therapy] excludes services furnished by a hospital or CAH directly or under arrangements'' (63 FR 30880). However, in the CY 1999 PFS final rule with comment period, the phrase ''or CAH'' was omitted from the final regulation text for OT in § 410.59(e)(3), but was included in the final regulation text for PT in § 410.60(e)(3). We note that for purposes of the therapy cap, outpatient PT services under our regulation at § 410.60 include outpatient SLP services described under § 410.62. As such, SLP services are included in the references to PT under § 410.60. Although the rulemaking history and regulations appear inconclusive as to whether outpatient therapy services furnished by CAHs were intended to be subject to the therapy caps between January 1, 1999 and October 1, 2012, we believe that we inadvertently omitted the phrase ''or CAH'' in the CY 1999 final regulation for the occupational therapy cap. Moreover, we have consistently excluded all outpatient therapy services furnished by CAHs from the therapy caps over this time frame, whether the services were PT, SLP, or OT.

Accordingly, from the outset of the therapy caps under section 1833(g) of the Act, therapy services furnished by CAHs have not been subject to the therapy caps. Thus, CAHs have not been required to use the exceptions process (including the KX modifier and other requirements) when furnishing medically necessary therapy services above the therapy caps; and therapy services furnished by CAHs above the threshold amounts have not been subject to the manual medical review process. Similarly, until section 603(b) of the ATRA amended the statute to specify the amount that must be counted towards the therapy caps and thresholds for outpatient therapy services furnished by CAHs, we did not apply towards the therapy caps or thresholds any amounts for therapy services furnished by CAHs. Therefore, we have interpreted the statutory exclusion for outpatient therapy services furnished by hospital outpatient departments also to apply to CAHs and implemented the therapy caps accordingly.

As noted above, section 3005(b) of the MCTRJCA temporarily suspended the outpatient hospital services exemption from October 1, 2012 through December 31, 2012 (which has subsequently been extended by the ATRA through December 31, 2013). As a result, from October 1, 2012 to the present, CAH services have been treated differently than services furnished in other outpatient hospital settings. In implementing this change required by the MCTRJCA, we had reason to assess whether, as a result of the amendment, the therapy caps should be applied to outpatient therapy services furnished by CAHs. We concluded that the MCTRJCA amendment did not make the therapy caps applicable to services furnished by CAHs for which payment is made under section 1834(g) of the Act because it affected only the outpatient hospital services described under section 1833(a)(8)(B) of the Act for which payment is made under section 1834(k)(1)(B) of the Act. With the enactment in section 603(b) of the ATRA of specific language requiring us to count amounts toward the therapy caps and thresholds for services furnished by CAHs, we again had reason to assess whether the therapy caps apply to services furnished by CAHs. We concluded that the ATRA amendment did not explicitly make the therapy caps applicable to services furnished by CAHs, but directed us to count CAH services towards the caps. However, after reflecting on the language of section 1833(g) of the Act, we have concluded that the therapy caps should be applied to outpatient therapy services furnished by CAHs.

To explain further, under sections 1833(g)(1) and (3) of the Act, the therapy caps are made applicable to all services described under section 1861(p) of the Act except those described under the outpatient hospital services exemption. Section 1861(p) of the Act establishes the benefit category for outpatient PT, SLP and OT services, (expressly for PT

services and, through section 1861(ll)(2) of the Act, for outpatient SLP services and, through section 1861(g) of the Act, for outpatient OT services). Section 1861(p) of the Act defines outpatient therapy services in the three disciplines as those furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient; and those furnished by a therapist not under arrangements with a provider of services, clinic, rehabilitation agency, or a public health agency. As such, section 1861(p) of the Act defines outpatient therapy services very broadly to include those furnished by providers and other institutional settings, as well as those furnished in office settings. Under section 1861(u) of the Act, a CAH is a ''provider of services.'' As such, unless the outpatient therapy services furnished by a CAH fit within the outpatient hospital services exemption under section 1833(a)(8)(B) of the Act, the therapy caps would be applicable to PT, SLP, OT services furnished by a CAH. As noted above, section 1833(a)(8)(B) of the Act describes only outpatient therapy services for which payment is made under section 1834(k) of the Act. Payment for CAH services is made under section 1834(g) of the Act. Thus, the outpatient hospital services exemption to the therapy caps under section 1833(a)(8)(B) of the Act does not apply, and the therapy caps are applicable, to outpatient therapy services furnished by a CAH.

However, we recognize that our current regulation specifically excludes PT and SLP services furnished by CAHs from the therapy caps, and our consistent practice since 1999 has been to exclude PT, SLP and OT services furnished by CAHs from the therapy caps. As such, in order to apply the therapy caps and related policies to services furnished by CAHs for CY 2014 and subsequent years, we believe we would need to revise our regulations.

We propose to apply the therapy cap limitations and related policies to outpatient therapy services furnished by a CAH beginning on January 1, 2014. Not only do we believe this is the proper statutory interpretation, but we also believe it is the appropriate policy. Under the existing regulations, with the suspension of the outpatient hospital services exemption through 2013, the therapy caps apply to outpatient therapy services paid under Medicare Part B and furnished in all applicable settings except CAHs. We believe that outpatient therapy services furnished by a CAH should be treated consistently with outpatient therapy services furnished in all other settings. Therefore, we propose to revise the therapy cap regulation at § 410.60(e)(3) to remove the exemption for services furnished by a CAH.

CAH outpatient therapy services are distinct from other outpatient therapy services in that outpatient therapy services furnished in office-based or other institutional settings are paid at the rates contained in the PFS, whereas CAHs are paid for outpatient therapy services under the methodology described under section 1834(g) of the Act. Because the CAH reasonable cost-based payment amounts are reconciled at cost reporting year-end, and are different from the fee schedule-based payments for other outpatient therapy services, it might have been difficult to identify the amounts that we should have accrued towards the therapy caps for services furnished by CAHs. Therefore, prior to 2013, not only did CMS not apply any caps to services provided by a CAH, but also did not count CAH services towards the caps. However, the ATRA amended the statute to require for outpatient therapy services furnished by CAHs during 2013 that we count towards the caps and the manual medical review thresholds the amount that would be payable for the services under Medicare Part B as if the services were paid as outpatient therapy services under section 1834(k)(1)(B) of the Act instead of as CAH services under section 1834(g) of the Act. Thus, the distinction in payment methodology no longer provides a technical barrier to including an amount for therapy services furnished by CAHs in the caps. We propose to continue this methodology of counting the amount payable under section 1834(k)(1)(B) of the Act towards the therapy cap and threshold for services furnished by CAHs in CY 2014 and subsequent years.

We recognize that the outpatient hospital services exemption is suspended under current law only through December 31, 2013. If this provision is not extended, with our proposal to apply the therapy caps to services furnished by CAHs, effective January 1, 2014, therapy services furnished by CAHs would be treated differently than services furnished in other outpatient hospital settings. We note that the exceptions process described above, including use of the KX modifier to attest to the medical necessity of therapy services above the caps and other requirements, would apply for services furnished by a CAH in the same way that it applies to outpatient therapy services furnished by certain other facilities. Similarly, the manual medical review process for claims that exceed the $3,700 thresholds would apply to therapy services furnished by a CAH in the same way that they apply for outpatient therapy services furnished by certain other facilities. We recognize that the manual medical review process expires on December 31, 2013 and we would apply the manual medical review process to CAH services only as required by statute. We are proposing to amend the regulations establishing the conditions for PT, OT, and SLP services by removing the exemption of CAH services from the therapy caps and specifying that the therapy caps apply to such services.

Specifically, we propose to amend the regulations, which pertain to the OT therapy cap and the combined PT and SLP therapy cap, respectively, by including paragraph (e)(1)(iv) under § 410.59 and (e)(1)(iv) under § 410.60 to specify that (occupational/physical) therapy services furnished by a CAH directly or under arrangements shall be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(B) of the Act. We also propose to add new paragraph (e)(2)(v) to § 410.59 and (e)(2)(vi) to § 410.60. These new paragraphs would expressly include outpatient (occupational/physical) therapy services furnished by a CAH directly or under arrangements under the description of services to which the annual limitation applies. Further, we propose to amend the regulation at § 410.60(e)(3), which currently excludes services furnished by a CAH from the therapy cap for PT and SLP services, to remove the phrase ''or CAH.''

H. Requirements for Billing ''Incident To'' Services

Section 1861(s)(2)(A) of the Act establishes the benefit category for services and supplies furnished as ''incident to'' the professional services of a physician. The statute specifies that ''incident to'' services and supplies are ''of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in physicians' bills.''

In addition to the requirements of the statute, our regulation at § 410.26 sets forth specific requirements that must be met in order for physicians and other practitioners to bill Medicare for incident to physicians' services. Section 410.26(a)(7) limits ''incident to'' services to those included under section 1861(s)(2)(A) of the Act and that are not covered under another benefit category. Section 410.26(b) specifies (in part) that

in order for services and supplies to be paid as ''incident to'' services under Medicare Part B, the services or supplies must be:

- Furnished in a noninstitutional setting to noninstitutional patients.
- An integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.
- Furnished under direct supervision (as specified under § 410.26(a)(2) and defined in § 410.32(b)(3)(ii)) of a physician or other practitioner eligible to bill and directly receive Medicare payment.
- Furnished by the physician, practitioner with an ''incident to'' benefit, or auxiliary personnel.

In addition to § 410.26, there are regulations specific to each type of practitioner who is allowed to bill for ''incident to'' services. These are found at § 410.71(a)(2) (clinical psychologist services), § 410.74(b) (physician assistants' services), § 410.75(d) (nurse practitioners' services), § 410.76(d) (clinical nurse specialists' services), and § 410.77(c) (certified nurse-midwives' services). When referring to practitioners who can bill for services furnished ''incident to'' their professional services, we are referring to physicians and these practitioners.

''Incident to'' services are treated as if they were furnished by the billing practitioner for purposes of Medicare billing and payment. Consistent with this terminology, in this discussion when referring to the practitioner furnishing the service, we mean the practitioner who is billing for the service. When we refer to the ''auxiliary personnel'' or the person who ''provides'' the service we are referring to an individual who is personally performing the service or some aspect of it. Since we treat ''incident to'' services as services furnished by the billing practitioner for purposes of Medicare billing and payment, payment is made to the billing practitioner under the PFS, and all relevant Medicare rules apply including, but not limited to, requirements regarding medical necessity, documentation, and billing. Those practitioners who can bill Medicare for ''incident to'' services are paid at their applicable Medicare payment rate as if they furnished the service. For example, when ''incident to'' services are billed by a physician, they are paid at 100 percent of the fee schedule amount, and when the services are billed by a nurse practitioner or clinical nurse specialist, they are paid at 85 percent of the fee schedule amount. Payments are subject to the usual deductible and coinsurance.

As the services commonly furnished in physicians' offices and other nonfacility settings have expanded to include more complicated services, the types of services that can be furnished ''incident to'' physicians' services have also expanded. States have increasingly adopted standards regarding the delivery of health care services in all settings, including physicians' offices, in order to protect the health and safety of their citizens. These state standards often include qualifications for the individuals who are permitted to furnish specific services or requirements about the circumstances under which services may be actually furnished. For example, since 2009, New York has required that offices in which surgery is furnished must be accredited by a state-approved accredited agency or organization. Similarly, Florida requires certain standards be met when surgery is furnished in offices, including that the surgeon must ''examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed'' and ''qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.''

Over the past years, several situations have come to our attention where Medicare was billed for ''incident to'' services that were provided by auxiliary personnel who did not meet the state standards for those services in the state in which the services were furnished. The physician or practitioner billing for the services would have been permitted under state law to personally furnish the services, but the services were actually provided by auxiliary personnel who were not in compliance with state law in providing the particular service (or aspect of the service).

Practitioners authorized to bill Medicare for services that they furnish to Medicare beneficiaries are required under Medicare to comply with state law. For example, section 1861(r) of the Act specifies that an individual can be considered a physician in the performance of any function or action only when legally authorized to practice in the particular field by the State in which he performs such function or action. Section 410.20(b) of our regulations provides that payment is made for services only if furnished by a doctor who is ''. . . legally authorized to practice by the state in which he or she performs the functions or actions, and who is acting within the scope of his or her license.'' Similarly, section 1861(s)(2)(K)(ii) of the Act provides a benefit category for services of a nurse practitioner (NP) or clinical nurse specialist (CNS) that the NP or CNS is ''legally authorized to perform by the State in which the services are performed, and § 410.75(b) of our regulations provides that nurse practitioners' services are covered only if the NP is ''authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law.'' There are similar provisions for clinical psychologist services (§ 410.71(a)(2)), clinical social worker services (§ 410.73(b)(1)), physician assistants' services (§ 410.74(a)(2)(ii)), clinical nurse specialists' services (§ 410.76(b)(1)), and certified nurse-midwives' services (§ 410.77(b)(1)).

However, the Medicare requirements for services and supplies incident to a physician's professional services (§ 410.26 discussed above), do not specifically make compliance with state law a condition of payment for services (or aspects of services) and supplies furnished and billed as ''incident to'' services. Nor do any of the regulations regarding services furnished ''incident to'' the services of other practitioners contain this requirement. Thus, Medicare has had limited recourse when services furnished incident to a physician's or practitioner's services are not furnished in compliance with state law.

In 2009, the Office of Inspector General issued a report entitled ''Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services'' (OEI–09–06–00430) that considered in part the qualifications of auxiliary personnel providing incident to physician services. This report found that services were being billed to Medicare that were provided by auxiliary personnel. After finding that services were being provided and billed to Medicare by auxiliary personnel ''. . . who did not possess the required licenses or certifications according to State laws, regulations, and/or Medicare rules,'' the OIG recommended that we revise the ''incident to'' rules to, among other things, ''require that physicians who do not personally perform the services they bill to Medicare ensure that no persons except . . . nonphysicians who have the necessary training, certification, and/or licensure, pursuant to State laws, State regulations, and Medicare regulations personally perform the services under the direct supervision of a licensed physician.'' We are also proposing amendments to our regulations to address this recommendation.

To ensure that auxiliary personnel providing services to Medicare

beneficiaries incident to the services of other practitioners do so in accordance with the requirements of the state in which the services are furnished and to ensure that Medicare dollars can be recovered when such services are not furnished in compliance with the state law, we are proposing to add a requirement to the ''incident to'' regulations at § 410.26, Services and supplies incident to a physician's professional services: Conditions. Specifically, we are proposing to amend § 410.26(b) by redesignating paragraphs (b)(7) and (b)(8) as paragraphs (b)(8) and (b)(9), respectively, and by adding a new paragraph (b)(7) to state that ''Services and supplies must be furnished in accordance with applicable State law.'' We are also proposing to amend the definition of auxiliary personnel at § 410.26(a)(1) to require that the individual performing ''incident to'' services ''meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.''

In addition, we are proposing to eliminate redundant and potentially incongruent regulatory language by replacing the specific ''incident to'' requirements currently contained in the regulations relating to each of the various types of practitioners with a reference to the requirements of § 410.26. Specifically, we are proposing to:

- Revise § 410.71(a)(2) regarding clinical psychologist services to read ''Medicare Part B covers services and supplies incident to the services of a clinical psychologist if the requirements of § 410.26 are met.''
- Revise § 410.74(b) regarding physician assistants' services to read ''Medicare Part B covers services and supplies incident to the services of a physician assistant if the requirements of § 410.26 are met.''
- Revise § 410.75(d) regarding nurse practitioners to read ''Medicare Part B covers services and supplies incident to the services of a nurse practitioner if the requirements of § 410.26 are met.''
- Revise § 410.76(d) regarding clinical nurse specialists' services to read with ''Medicare Part B covers services and supplies incident to the services of a clinical nurse specialist if the requirements of § 410.26 are met.''
- Revise the language in § 410.77(c) regarding certified nurse-midwives' services to read ''Medicare Part B covers services and supplies incident to the services of a certified nurse-midwife if the requirements of § 410.26 are met.''

As discussed above, these practitioners are, and would continue to be under this proposal, required to comply with § 410.26 for services furnished incident to their professional services. We believe it is redundant and potentially confusing to have separate regulations that generally restate the requirements for ''incident to'' services of § 410.26 using slightly different terminology. Our goal in proposing the revisions to refer to § 410.26 in the regulation for each practitioner's ''incident to'' services is to reduce the regulatory burden and make it less difficult for practitioners to determine what is required. Reconciling these regulatory requirements for physicians and all other practitioners who have the authority to bill Medicare for ''incident to'' services is also consistent with our general policy to treat nonphysician practitioners similarly to physicians unless there is a compelling reason for disparate treatment. We believe that this proposal would make the requirements clearer for practitioners furnishing ''incident to'' services without eliminating existing regulatory requirements or imposing new ones. We welcome comments on any requirements that we may have inadvertently overlooked in our proposed revisions, or any benefit that accrues from continuing to carry these separate regulatory requirements.

The regulations applicable to Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) have similar ''incident to'' rules, and we are proposing to make conforming changes to these regulations. Specifically, we are also proposing to revise § 405.2413(a), which addresses services and supplies incident to physicians' services for RHCs and FQHCs, by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4) that states services and supplies must be furnished in accordance with applicable state law. Additionally, we are proposing to amend § 405.2415(a), which addresses services incident to nurse practitioner and physician assistant services by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4) that specifies services and supplies must be furnished in accordance with applicable state law. We are proposing to amend § 405.2452(a), which addresses services and supplies incident to clinical psychologist and clinical social worker services by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4) that states services and supplies must be furnished in accordance with applicable state law. Finally, we are also proposing the removal of the word ''personal'' in §§ 405.2413, 405.2415, and 405.2452 to be consistent with the ''incident to'' provisions in § 410.26 Services and supplies incident to a physician's professional services: Conditions.

The proposed amendments to our regulations are consistent with the traditional approach of relying primarily on the states to regulate the health and safety of their residents in the delivery of health care services. Throughout the Medicare program, as evidenced by several examples above, the qualifications required for the delivery of health care services are generally determined with reference to state law. As discussed above, our current regulations governing practitioners who can bill Medicare directly include a basic requirement to comply with state law when furnishing Medicare covered services. However, the Medicare regulations for ''incident to'' services and supplies do not specifically make compliance with state law a condition of payment for services and supplies furnished and billed as an incident to a practitioner's services. The proposed amendments to our regulations would rectify this situation and make compliance with state law a requirement for all ''incident to'' services. In addition to health and safety benefits we believe would accrue to the Medicare patient population, this approach would assure that federal dollars are not expended for services that do not meet the standards of the states in which they are being furnished, and provides the ability for the federal government to recover funds paid where services and supplies are not furnished in accordance with state law.

We note that this proposal would not impose any new requirements on those practitioners billing the Medicare program since auxiliary personnel furnishing services in a state would already be required to comply with the laws of that state. This regulatory change would simply adopt the existing requirements as a condition of payment under Medicare. Codifying this requirement would provide the federal government a clear basis to deny a claim for Medicare payment when services are not furnished in accordance with applicable state law and the ability to recover funds, as well as assure that Medicare makes payment for services furnished to beneficiaries only when the services meet the requirements imposed by the states to regulate health care delivery in order to ensure the health and safety of their citizens.

I. Complex Chronic Care Management Services

As we discussed in the CY 2013 PFS final rule with comment period, we are committed to primary care and we have increasingly recognized care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth (77 FR 68978). Accordingly, we have prioritized the development and implementation of a series of initiatives designed to improve payment for, and encourage long-term investment in, care management services. These initiatives include the following programs and demonstrations:

- The Medicare Shared Savings Program (described in ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule'' which appeared in the November 2, 2011 **Federal Register** (76 FR 67802)).
- The testing of the Pioneer ACO model, designed for experienced health care organizations (described on the Center for Medicare and Medicaid Innovation's (Innovation Center's) Web site at *innovations.cms.gov/initiatives/ACO/Pioneer/index.html*).
- The testing of the Advance Payment ACO model, designed to support organizations participating in the Medicare Shared Savings Program (described on the Innovation Center's Web site at *innovations.cms.gov/initiatives/ACO/Advance-Payment/index.html*).
- The Primary Care Incentive Payment (PCIP) Program (described on the CMS Web site at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/PCIP-2011-Payments.pdf*).
- The patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration designed to test whether the quality and coordination of health care services are improved by making advanced primary care practices more broadly available (described on the CMS Web site at *www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf*).
- The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration (described on the CMS Web site at *www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf* and the Innovation Center's Web site at *innovations.cms.gov/initiatives/FQHCs/index.html*).
- The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's Web site at *innovations.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html*). The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care in certain markets across the country.

In coordination with these initiatives, we also continue to explore potential refinements to the PFS that would appropriately value care management within Medicare's statutory structure for fee-for-service physician payment and quality reporting. For example, in the CY 2013 PFS final rule with comment period, we adopted a policy to pay separately for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay to care furnished by the beneficiary's primary physician in the community (77 FR 68978 through 68993). We view potential refinements to the PFS such as these as part of a broader strategy that relies on input and information gathered from the initiatives described above, research and demonstrations from other public and private stakeholders, the work of all parties involved in the potentially misvalued code initiative, and from the public at large.

1. Patient Eligibility for Separately Payable Non-Face-to-Face Complex Chronic Care Management Services

Under current PFS policy, the payment for non-face-to-face care management services is bundled into the payment for face-to-face E/M visits because care management is a component of those E/M services. The pre- and post-encounter non-face-to-face care management work is included in calculating the total work for the typical E/M services, and the total work for the typical service is used to develop RVUs for the E/M services. In the CY 2012 PFS proposed rule, we highlighted some of the E/M services that include substantial care management work. Specifically, we noted that the vignettes that describe a typical service for mid-level office/outpatient services (CPT codes 99203 and 99213) include furnishing care management, communication, and other necessary care management related to the office visit in the post-service work (76 FR 42917).

However, the physician community continues to tell us that the care management included in many of the E/M services, such as office visits, does not adequately describe the typical non-face-to-face care management work involved for certain categories of beneficiaries. Because the current E/M office/outpatient visit CPT codes were designed to support all office visits and reflect an overall orientation toward episodic treatment, we agree that these E/M codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries. For example, we currently pay physicians separately for the non face-to-face care plan oversight services furnished to beneficiaries under the care of home health agencies or hospices and we currently pay separately for care management services furnished to beneficiaries transitioning from care furnished by a treating physician during a hospital stay to care furnished by the beneficiary's primary physician in the community.

Similar to these situations, we believe that the resources required to furnish complex chronic care management services to beneficiaries with multiple (that is, two or more) chronic conditions are not adequately reflected in the existing E/M codes. Furnishing care management to beneficiaries with multiple chronic conditions requires complex and multidisciplinary care modalities that involve: Regular physician development and/or revision of care plans; subsequent reports of patient status; review of laboratory and other studies; communication with other health professionals not employed in the same practice who are involved in the patient's care; integration of new information into the care plan; and/or adjustment of medical therapy. Therefore, for CY 2015, we are proposing to establish a separate payment under the PFS for complex chronic care management services furnished to patients with multiple complex chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

We have performed an analysis of Medicare claims for patients with selected multiple chronic conditions (see *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf*). This analysis indicated that patients with these selected multiple chronic conditions are at increased risk for hospitalizations, use of post-acute care services, and emergency department visits. We believe these findings would hold in general for patients with multiple

complex chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. We believe that successful efforts to improve chronic care management for these patients could improve the quality of care while simultaneously decreasing costs (for example, through reductions in hospitalizations, use of post-acute care services, and emergency department visits.)

As described below in more detail in section II.I.3, we intend to develop standards for furnishing complex chronic care management services to ensure that the physicians who bill for these services have the capability to provide them. One of the primary reasons for our proposed 2015 implementation date is to provide sufficient time to develop and obtain public input on the standards necessary to demonstrate the capability to provide these services.

2. Scope of Complex Chronic Care Management Services

We consider the scope of complex chronic care management services to include:

- The provision of 24-hour-a-day, 7-day-a-week access to address a patient's acute complex chronic care needs. To accomplish these tasks, we would expect that the patient would be provided with a means to make timely contact with health care providers in the practice to address urgent complex chronic care needs regardless of the time of day or day of the week. Members of the complex chronic care team who are involved in the after-hours care of a patient must have access to the patient's full electronic medical record even when the office is closed so they can continue to participate in care decisions with the patient.
- Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments.
- Care management for chronic conditions including systematic assessment of patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications. In consultation with the patient and other key practitioners treating the patient, the practitioner furnishing complex chronic care management services should create a patient-centered plan of care document to assure that care is provided in a way that is congruent with patient choices and values. A plan of care is based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health issues. It typically includes, but is not limited to, the following elements: Problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention, requirements for periodic review and, when applicable, revision, of the care plan. The provider should seek to reflect a full list of problems, medications and medication allergies in the electronic health record to inform the care plan, care coordination and ongoing clinical care.
- Management of care transitions within health care including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and skilled nursing facilities. The practice must be able to facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The practice must also have qualified personnel who are available to deliver transitional care services to a patient in a timely way so as to reduce the need for repeat visits to emergency departments and re-admissions to hospitals and skilled nursing facilities.
- Coordination with home and community based clinical service providers required to support a patient's psychosocial needs and functional deficits. Communication to and from home and community based providers regarding these clinical patient needs must be documented in practice's medical record system.
- Enhanced opportunities for a patient to communicate with the provider regarding their care through not only the telephone but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.

3. Standards for Furnishing Complex Chronic Care Coordination Services

Not all physicians and qualified nonphysician practitioners who wish to furnish complex chronic care management services currently have the capability to fully provide the scope of services described in section II.I.2. without making additional investments in technology, staff training, and the development and maintenance of systems and processes to furnish the services. We intend to establish standards that would be necessary to provide high quality, safe complex chronic care management services. For example, potential standards could include the following:

- The practice must be using a certified Electronic Health Record (EHR) for beneficiary care that meets the most recent HHS regulatory standard for meaningful use. The EHR must be integrated into the practice to support access to care, care coordination, care management and communication.
- The practice must employ one or more advanced practice registered nurses or physicians assistants whose written job descriptions indicate that their job roles include and are appropriately scaled to meet the needs for beneficiaries receiving services in the practice who require complex chronic care management services provided by the practice.
- The practice must be able to demonstrate the use of written protocols by staff participating in the furnishing of services that describe: (1) The methods and expected ''norms'' for furnishing each component of complex chronic care management services provided by the practice; (2) the strategies for systematically furnishing health risk assessments to identify all beneficiaries eligible and who may be willing to participate in the complex chronic care management services; (3) the procedures for informing eligible beneficiaries about complex chronic care management services and obtaining their consent; (4) the steps for monitoring the medical, functional and social needs of all beneficiaries receiving complex chronic care management services; (5) system based approaches to ensure timely delivery of all recommended preventive care services to beneficiaries; (6) guidelines for communicating common and anticipated clinical and non-clinical issues to beneficiaries; (7) care plans for beneficiaries post-discharge from an emergency department or other institutional health care setting, to assist beneficiaries with follow up visits with clinical and other suppliers or providers, and in managing any changes in their medications; (8) a systematic approach to communicate and electronically exchange clinical information with and coordinate care among all service providers involved in

the ongoing care of a beneficiary receiving complex chronic care management services; (9) a systematic approach for linking the practice and a beneficiary receiving complex chronic care management services with long-term services and supports including home and community-based services; (10) a systematic approach to the care management of vulnerable beneficiary populations such as racial and ethnic minorities and people with disabilities; and (11) patient education to assist the beneficiary to self-manage a chronic condition that is considered at least one of his/her complex chronic conditions. These protocols must be reviewed and updated as is appropriate based on the best available clinical information at least annually.

• All practitioners including advanced practice registered nurses or physicians assistants, involved in the delivery of complex chronic care management services must have access at the time of service to the beneficiary's EHR that includes all of the elements necessary to meet the most recent HHS regulatory standard for meaningful use. This includes any and all clinical staff providing after hours care to ensure that the complex chronic care management services are available with this level of EHR support in the practice or remotely through a Virtual Private Network (VPN), a secure Web site, or a health information exchange (HIE) 24 hours per day and 7 days a week.

Some have suggested that, to furnish these services, practices could be recognized as a medical home by one of the national organizations including: the National Committee for Quality Assurance (NCQA), the Accreditation Association for Ambulatory Health Care, The Joint Commission, URAC, etc.; which are formally recognizing primary care practices as a patient-centered medical home. We understand there are differences among the approaches taken by national organizations that formally recognize medical homes and therefore, we seek comment on these and other potential care coordination standards, and the potential for CMS recognizing a formal patient-centered medical home designation as one means for a practice to demonstrate it has met any final care coordination standards for furnishing complex chronic care management services. Any regulatory changes would be addressed through separate notice-and-comment rulemaking.

4. Billing for Separately Payable Complex Chronic Care Management Services and Obtaining Informed Consent From the Beneficiary

To recognize the additional resources required to provide complex chronic care management services to patients with multiple chronic conditions, we are proposing to create two new separately payable alphanumeric G-codes.

Complex chronic care management services furnished to patients with multiple (two or more) complex chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;

GXXX1, initial services; one or more hours; initial 90 days

GXXX2, subsequent services; one or more hours; subsequent 90 days

Typically, we would expect the one or more hours of services to be provided by clinical staff directed by a physician or other qualified health care professional. Initial services include obtaining the initial informed consent from the beneficiary as described below and the initial implementation of the complex chronic care management services described in section II.I.2. of this proposed rule.

Not all patients who are eligible for separately payable complex chronic care management services may necessarily want these services to be provided. Therefore, before the practitioner can furnish or bill for these services, the eligible beneficiary must be informed about the availability of the services from the practitioner and provide his or her consent to have the services provided, including the electronic communication of the patient's information with other treating providers as part of care coordination. This would include a discussion with the patient about what complex chronic care management services are, how these services are accessed, how their information will be shared among other providers in the care team, and that cost-sharing applies to these services even when they are not delivered face-to-face in the practice. To bill for the initial services (GXXX1), the practitioner would be required to document in the patient's medical record that all of the complex chronic care management services were explained and offered to the patient, noting the patient's decision to accept these services. Also, a written or electronic copy of the care plan would be provided to the beneficiary and this would also be recorded in the beneficiary's electronic medical record.

A practitioner would need to reaffirm with the beneficiary at least every 12 months whether he or she wishes to continue to receive complex chronic care management services during the following 12-month period.

The informed consent for complex chronic care management services could be revoked by the beneficiary at any time. However, if the revocation occurs during a current 90-day complex chronic care management period, the revocation would not be effective until the end of that period. The beneficiary could notify the practitioner either verbally or in writing. At the time the informed consent is obtained, the practitioner would be required to inform the beneficiary of the right to stop the complex chronic care management services at any time and the effect of a revocation of consent on complex chronic care management services. Revocation by the beneficiary of the informed consent must also be noted by recording the date of the revocation in the beneficiary's medical record and by providing the beneficiary with written confirmation that the practitioner would not be providing complex chronic care management services beyond the current 90 day period.

A beneficiary who has revoked informed consent for complex chronic care management services from one practitioner may choose instead to receive these services from a different practitioner, which can begin at the conclusion of the current 90-day period. The new practitioner would need to fulfill all the requirements for billing GXXX1 and then GXXX2.

Prior to submitting a claim for complex chronic care management services, the practitioner must notify the beneficiary that a claim for these services will be submitted to Medicare. The notification must indicate: that the beneficiary has been receiving these services over the previous 90-day period (noting the beginning and end dates for the 90-day period), the reason(s) why the services were provided and a description of the services provided. The notice may be delivered by a means of communication mutually agreed to by the practitioner and beneficiary such as mail, email, or facsimile, or in person (for example, at the time of an office visit.) The notice must be received by the beneficiary before the practitioner submits the claim for the services. A separate notice must be received by the beneficiary for each 90-day period for which the services will be billed. A copy of the notice should be included in the medical record.

In addition to the requirement that at least an hour of complex chronic care

management services be furnished to the patient, we propose that billing for subsequent complex chronic care management services (GXXX2) would be limited to those 90-day periods in which the medical needs of the patient require substantial revision of the care plan discussed in section II.I.2. Substantial revision to a care plan typically is required when the patient's clinical condition changes sufficiently to require: Significantly more intensive monitoring by clinical staff, significant changes in the treatment regimen, and significant time to educate the patient/caregiver about the patient's condition/change in treatment plan and prognosis.

Because the payment for non-face-to-face care management services is generally bundled into the payment for face-to-face E/M visits, the resources required to provide care management services for patients without multiple chronic conditions or for less than the one or more hours of clinical staff time continues to be reflected in the payment for face-to-face E/M visits. For similar reasons, the resources required to provide care management services to patients residing in facility settings where care management activity by facility staff would be included in the associated facility payment also continues to be reflected in the payment for face-to-face E/M visits.

We propose that complex chronic care management services include transitional care management services (CPT 99495, 99496), home health care supervision (HCPCS G0181), and hospice care supervision (HCPCS G0182). If furnished, in order to avoid duplicate payment, we propose that these services may not be billed separately during the 90 days for which either GXXX1 or GXXX2 are billed. For similar reasons, we propose that GXXX1 or GXXX2 cannot be billed separately if ESRD services (CPT 90951–90970) are billed during the same 90 days.

Practitioners billing a complex chronic care management code accept responsibility for managing and coordinating the beneficiary's care over this period. Therefore, we propose to pay only one claim for the complex chronic care management services (either GXXX1 or GXXX2) billed per beneficiary at the conclusion of each 90-day period. All of the complex chronic care management services delineated in section II.H.2 above that are relevant to the patient must be furnished in order to bill GXXX1 or GXXX2 for a 90-day period.

If a face-to-face visit is provided during the 90-day period by the practitioner who is furnishing complex chronic care management services, the practitioner should report the appropriate evaluation and management code in addition to GXXX1 or GXXX2.

We note that to bill for these services, we propose that at least 60 minutes of complex chronic care management services must be provided. Time of less than 60 minutes over the 90 day period could not be rounded up to 60 minutes in order to bill for these services. We also propose that for purposes of meeting the 60-minute requirement, the practitioner could count the time of only one clinical staff member for a particular segment of time, and could not count overlapping intervals such as when two or more clinical staff members are meeting about the patient.

In future rulemaking, we intend to propose RVUs for complex chronic care management services. To inform our proposal, we seek input on the physician work and practice expenses associated with these services.

5. Complex Chronic Care Management Services and the Annual Wellness Visit (AWV) (HCPCS codes G0438, G0439)

We are proposing that a beneficiary must have received an AWV in the past twelve months in order for a practitioner to be able to bill separately for complex chronic care management services. We believe that the linking of these services to the AWV makes sense for several reasons. First, the AWV is designed to enable a practitioner to systematically capture information that is essential for the development of a care plan. This includes the establishment of a list of current practitioners and suppliers that are regularly involved in providing medical care to the beneficiary, the assessment of the beneficiary's functional status related to chronic health conditions, the assessment of whether the beneficiary suffers from any cognitive limitations or mental health conditions that could impair self-management of chronic health conditions, and an assessment of the beneficiary's preventive health care needs including those that contribute to or result from a beneficiary's chronic conditions. Second, the beneficiary's selection of a practitioner to furnish the AWV is a useful additional indicator to assist us in knowing which single practitioner a beneficiary has chosen to furnish complex chronic care management services. While a beneficiary would retain the right to choose and change the practitioner to furnish complex chronic care management services, we do not believe that it is in the interest of a beneficiary to have more than one practitioner at a time coordinating the beneficiary's care and we do not intend to pay multiple practitioners for furnishing these services over the same time period. Third, the AWV is updated annually which is consistent with the minimal interval for reviewing and modifying the care plan required for the complex chronic care management services.

We would expect that the practitioner the beneficiary chooses for the AWV would be the practitioner furnishing the complex chronic care management services. For the less frequent situations when a beneficiary chooses a different practitioner to furnish the complex chronic care management services from the practitioner who in the previous year furnished the AWV, the practitioner furnishing the complex chronic are management services would need to obtain a copy of the assessment and care plan developed between the beneficiary and the practitioner who furnished the AWV prior to billing for complex chronic care management services.

Because a beneficiary is precluded from receiving an AWV within 12 months after the effective date of his or her first Medicare Part B coverage period, for that time period we propose the Initial Preventive Physical Examination (G0402) can substitute for the AWV to allow a beneficiary to receive complex chronic care management services.

6. Complex Chronic Care Management Services Furnished Incident to a Physician's Service Under General Physician Supervision

We outline the requirements for billing for services furnished in the office, but not personally and directly performed by the physician or qualified nonphysician practitioner (referred to as a ''practitioner'' in the following discussion), under our ''incident to'' requirements in regulations and in section 60, Chapter 12, of Medicare Benefit Policy Manual (100–02). One key requirement of ''incident to'' services is that a practitioner (as the term is used in section II.H of this proposed rule directly supervise the provision of services by auxiliary personnel by being in the office suite and able to furnish assistance and direction throughout the provision of the service. Section 60.4 of the Manual specifically discusses the one exception that allows for general supervision of ''incident to'' services furnished to homebound patients in medically underserved areas. Under that provision, we identify more specific requirements for the personnel that can furnish ''incident to'' services under general supervision. For example, we require that the personnel must be

employed by, employed by the same entity, or an independent contractor of, the practitioner billing the ''incident to'' services.

One of the required capabilities for a physician to furnish complex chronic care management services is 24-hour-a-day, 7-day-a-week beneficiary access to the practice to address the patient's complex chronic care needs. We would expect that the patient would be provided with a means to make timely contact with health care providers in the practice to address those needs regardless of the time of day or day of the week. If the patient has a complex chronic care need outside of the practice's normal business hours, the patient's initial contact with the practice for that need could be with clinical staff employed by the practice, (for example, a nurse or other appropriate auxiliary personnel) and not necessarily with a physician or practitioner. Those services would be furnished incident to the services of the billing practitioner.

We have also proposed to require that at least one hour of complex chronic care services be furnished to a patient during the 90-day period in order for the practitioner to be able to bill separately for the chronic care services. The time, if not personally performed by the physician, must be directed by the physician. We are proposing that the time spent by a clinical staff person furnishing aspects of complex chronic care services outside of the practice's normal business hours during which there is no direct physician supervision would count towards the one hour requirement even though the services do not meet the direct supervision requirement for ''incident to'' services.

We believe that the additional requirements we impose for personnel under the exception for general supervision for homebound patients in medically underserved areas should apply in these circumstances where we are allowing a practitioner to bill Medicare for complex chronic care management services furnished under their general supervision and incident to their professional services. In both of these unusual cases, these requirements help to ensure that appropriate services are being furnished by appropriate personnel in the absence of the direct supervision. Specifically, we propose that if a practice meets all the conditions required to bill separately for complex chronic care management services, the time spent by a clinical staff employee furnishing aspects of these services to address a patient's complex chronic care need outside of the practice's normal business hours is counted towards the one hour requirement when at a minimum the following conditions are met:

- The clinical staff person is directly employed by the physician and the employed clinical staff person meets any relevant state requirements.
- The services of the clinical staff person are an integral part of the physician's complex chronic care management services to the patient (the patient must be one the physician is treating and for which informed consent is in effect), and are performed under the general supervision of the physician. General supervision means that the physician need not be physically present when the services are performed; however, the services must be performed under the physician's overall supervision and control. Contact is maintained between the clinical staff person and the physician (for example, the employed clinical staff person contacts the physician directly if warranted and the physician retains professional responsibility for the service.)
- The services of the employed clinical staff person meet all other ''incident to'' requirements with the exception of direct supervision.

7. Complex Chronic Care Management Services and the Primary Care Incentive Payment Program (PCIP)

Under section 1833(x) of the Act, the PCIP provides a 10 percent incentive payment for primary care services within a specific range of E/M services when furnished by a primary care practitioner. Specific physician specialties and qualified nonphysician practitioners can qualify as primary care practitioners if 60 percent of their PFS allowed charges are primary care services. As we explained in the CY 2011 PFS final rule (75 FR 73435 through 73436), we do not believe the statute authorizes us to add codes (additional services) to the definition of primary care services. However, to avoid inadvertently disqualifying community primary care physicians who follow their patients into the hospital setting, we finalized a policy to remove allowed charges for certain E/M services furnished to hospital inpatients and outpatients from the total allowed charges in the PCIP primary care percentage calculation. In the CY 2013 final rule (77 FR 68993), we adopted a policy that the TCM code should be treated in the same manner as those services for the purposes of PCIP because post-discharge TCM services are a complement in the community setting to the hospital-based discharge day management services already excluded from the PCIP denominator. Similar to the codes already excluded from the PCIP denominator, we expressed concern that inclusion of the TCM code in the denominator of the primary care percentage calculation could produce unwarranted bias against ''true primary care practitioners'' who are involved in furnishing post-discharge care to their patients.

Complex chronic care management services are also similar to the services that we have already excluded from the from the PCIP denominator. For example, complex chronic care management includes management of care transitions within health care settings including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and skilled nursing facilities. Therefore, while physicians and qualified nonphysician practitioners who furnish complex chronic care management services would not receive an additional incentive payment under the PCIP for the service itself (because it is not considered a ''primary care service'' for purposes of the PCIP), we propose that the allowed charges for complex chronic care management services would not be included in the denominator when calculating a physician's or practitioner's percent of allowed charges that were primary care services for purposes of the PCIP.

8. Summary

In summary, we are proposing for CY 2015 to establish a separate payment under the PFS for complex chronic care management services furnished to patients with multiple complex chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, as discussed in section II.I.1. We are proposing the scope of these complex chronic care management services discussed in section II.I.2; the billing requirements for these services as discussed in section II.I.4; the AWV requirement as discussed in section II.I.5; the general supervision requirements as discussed in section II.I.6, and the PCIP denominator exclusion as discussed in section II.I.7.

We are seeking input from the public on, the standards required to provide these services as discussed in section II.I.3, and the work and PE that would be associated with these services.

We are making this proposal to establish codes and separate payment for complex chronic care management services in the context of the broader

multi-year strategy to appropriately recognize and value primary care and care management services. Should this proposal become final policy, it may be a short-term payment strategy that would be modified and/or revised to be consistent with broader primary care, and care management and coordination services if the agency decides to pursue payment for a broader set of management and coordination services in future rulemaking. We also note that as we consider a final policy, we would assess the potential impact of the policy on our current programs and demonstrations designed to improve payment for, and encourage long-term investment in, care management services. Likewise, to assure that there are not duplicate payments for delivery of care management services, we would consider whether such payments are appropriate for providers participating in other programs and demonstrations.

J. Chiropractors Billing for Evaluation and Management Services

Section 1861(r)(5) of the Act includes chiropractors in its definition of ''physician'' with language limiting chiropractors to ''treatment by means of manual manipulation of the spine (to correct a subluxation).'' Specifically, the Act says:

> The term ''physician,'' when used in connection with the performance of any function or actions means . . . a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services) and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform the State or jurisdiction in which such treatment is provided.

The statute, thus, limits chiropractic coverage to treatment of subluxation of the spine. Our interpretation of this language allows payment to chiropractors for chiropractic manual manipulation to correct a subluxation of the spine. Specifically, we provide for payment of the following codes listed in the chiropractic section of the CPT Manual.

98940—Chiropractic manipulation treatment (CMT), spinal, 1–2 regions
98941—CMT spinal, 3–4 regions
98942—CMT spinal, 5 regions

(CPT includes an additional CPT code 98943—CMT extraspinal 1 or more regions for which Medicare does not cover as it is not a spinal manipulation.)

Section 240.1.2 of the IOM 100–02 includes requirements that must be met to demonstrate that these services are necessary, using either x-ray or physical examination. In addition, it includes documentation requirements for initial and subsequent visits. These include a history and physical exam.

According to the CPT manual, the codes for CMT describe services including a ''pre-manipulative patient assessment,'' which is consistent with the history and physical exam requirement discussed above. In determining the relative value assigned to the CMT services we include this pre-manipulative patient assessment.

These chiropractic codes have a global surgery indicator of 0, meaning that we do not pay separately for services provided on the same day and related to the same service. The CPT manual notes that separate E/M services can be reported with a -25 modifier ''if the patient's condition requires a significant, separately identified E/M service above and beyond the usual preservice and postservice work associated with the procedures.'' It goes on to note that a separate diagnosis is not required.

We currently do not allow payment for E/M services to chiropractors as we have not identified an E/M service that would be related to treatment of subluxation of the spine, which is the statutory requirement, beyond the preservice and postservice work associated with the CMT. We have believed that the assessments included in the CMT codes accurately capture the E/M that would typically be furnished by chiropractors in furnishing CMT services.

Questions have arisen as to whether it would be appropriate to allow chiropractors to furnish and bill Medicare for E/M services, especially in light of the CPT language regarding the reporting of a separate E/M service on the same day using a -25 modifier. We would note that CPT codes are the HIPPA compliant code set. Their use is not limited to Medicare, and other insurers may not limit chiropractic coverage to manual manipulation to correct subluxation of the spine. We are seeking comment to assess whether there are situations in which E/M services that are not included in the CMT codes, but would meet the statutory requirements for chiropractor services, would be appropriate. We are not proposing to pay chiropractors for E/M services in CY 2014. If after receiving and analyzing public comment we determine that it would be appropriate to modify our policy with respect to chiropractors and E/M services, we would do so in future rulemaking.

Specifically, we are seeking comments on the following questions:

- Are there situations where a chiropractor would furnish E/M services that are with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) that are not included within the definition of the CMT codes? Specifically, we are seeking information on the situations, the services that would be provided, and the E/M codes that would be billed.
- Would such a policy expand access to chiropractic services for Medicare beneficiaries? Are there other benefits that would accrue?
- If payment were to be allowed for E/M services, which codes would be appropriate to report chiropractic E/M services? For services provided in an office, would it be appropriate to allow billing of all five office E/M codes for new or existing patient as appropriate? Should one or a set of codes be created specifically for chiropractic E/M services similar to those for therapy evaluations or ophthalmic evaluations? With what frequency should chiropractors be allowed to bill E/M services?
- What would justify E/M services beyond those included in CMT codes? Should they be allowed on every treatment day or only at the onset of treatment?
- Are these E/M services ones that are already being furnished by another physician or other practitioner? If these are not services currently covered by Medicare, what volume could be expected?

III. Other Provisions of the Proposed Regulations

A. Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage

1. Statutory Authority and Background

This proposed rule would revise certain Medicare regulations currently codified in § 405.201 through 405.214, and § 411.15(o) relating to coverage of the costs of routine items and services in Category A Investigational device exemption (IDE) studies and trials, and coverage of the costs of Category B, investigational devices and the costs of routine items and services in Category B investigational device exemption (IDE) studies and trials. It is based on section 1862(m) of the Act, which, among other things, authorizes the Secretary to establish criteria to ensure that studies and trials of Category A devices conform to appropriate scientific and ethical

standards. We are proposing to establish those criteria that ensure that studies and trials of Category A devices conform to appropriate scientific and ethical standards. We are also proposing, based on our rulemaking authority in section 1871 of the Act, to extend the same criteria proposed for Category A IDE studies and trials to Category B IDE studies and trials. Our proposed rules are necessary to carry out the administration of the insurance program under Title XVIII of the Act). Finally, to ensure that coverage of items and services in IDE studies and trials is uniform across Medicare administrative regions, we are proposing that IDE coverage decisions will be made by CMS centrally.

On September 8, 1995, the FDA and CMS (then known as HCFA) entered into an interagency agreement in which the FDA agreed to categorize investigational device exemptions (IDEs) for purposes of Medicare coverage. The process identified in this interagency agreement is reflected in a September 19, 1995 final rule (60 FR 48417). The September 19, 1995 rule described two FDA device categories: (1) Category A devices were described as experimental/investigational devices; and (2) Category B devices were described as nonexperimental/investigational devices.

a. Coverage of IDE—Costs of Routine Items, Services, and Devices

The September 19, 1995 rule created a path to Medicare coverage under certain circumstances for Category B investigational devices and the costs of routine items and services in IDE studies and trials. The IDE coverage policy gave Medicare beneficiaries the opportunity to have earlier access to new medical devices, but these determinations were made by local Medicare contractors sometimes on a claim-by-claim basis. Although the current IDE policy was a path to earlier access to certain devices and the costs of routine items and services, we were also hearing that the IDE coverage approval process was burdensome and created national variability that made it difficult for study sponsors to conduct national IDE studies.

As we evaluated the IDE review and approval process we heard and sought out feedback from stakeholders (for example, manufacturers, study sponsors, and hospitals). Most of the stakeholders told us that obtaining coverage of the device and the costs of routine items and services was inefficient; that each Medicare contractor has different processes to review IDE devices and studies. It also became apparent that the lack of centralization led to inconsistent IDE coverage across the Medicare contractors. These factors contributed to some reluctance to enroll Medicare beneficiaries in IDE studies.

We also requested feedback from the Medicare local contractors. We found that the Medicare contractors reviewed pertinent available evidence and the FDA-approved IDE study protocol as factors in their decision-making process. Reviewing all of the information related to the IDE device and the FDA-approved study was a way to ensure that the device, as used, is reasonable and necessary for the Medicare beneficiary and furnished in a setting appropriate to the patient's medical needs. While each contractor's process was appropriate, they were in practice slightly different from contractor to contractor; and in most cases duplicative. Furthermore, we found that local Medicare contractors were applying varying levels of scrutiny in reviewing IDE devices and the costs of routine items and services within IDE studies. Most contractors reviewed IDE study protocols extensively, while other contractors may have reviewed them less extensively.

2. Proposals

We are proposing a transparent, centralized review process that would be more efficient by reducing the burden for stakeholders interested in conducting nationwide trials. Once the IDE coverage process is centralized, there would be a single entity making the IDE coverage decision. This enhances administrative efficiency by eliminating the need for duplicative reviews by Medicare local contractors and the submission of duplicated coverage requests to different contractors by stakeholders. We believe that a centralized review process would not significantly reduce the number of IDE devices currently covered; but we are specifically requesting public to comment on this issue. Changing the review and decision of IDE coverage to a centralized review process in no way changes any beneficiary appeal rights.

a. Category A IDE Devices

In 2003, section 731(b) of the Prescription Drug, Improvement, and Modernization Act (MMA) provided that the Secretary could not exclude coverage for certain routine care costs in IDE studies and trials of Category A devices, provided to beneficiaries under section 1862(a)(1)(A) of the Act. A Category A IDE device is a device for which the initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective. In addition, the Secretary was given the authority to ensure that any Category A IDE device study conform to appropriate scientific and ethical standards (section 1862(m)(1) of the Act). While the Congress gave the Secretary the authority to determine the scope of routine care costs, the Congress did not authorize or establish coverage for the Category A device itself. Therefore, we are not proposing any changes to coverage of the Category A IDE device. Category A devices would continue to be noncovered under section 1862(a)(1)(A) of the Act.

The Congress has expressly authorized the Secretary to establish criteria to ensure that any Category A IDE device study conform to appropriate scientific and ethical standards. (For more information, see section 1862(m)(2)(B) of the Act.) In the November 15, 2004 conforming final rule (69 FR 66420), we finalized a regulatory provision at § 405.207(b)(2) requiring Category A IDE devices be furnished in conjunction with an FDA-approved clinical study and that the study standards would be defined through the national coverage determination (NCD) process. Rather than establish standards through the NCD process, we would specify the study standards in this proposed rule. We believe the Congress gave the Secretary the authority to create appropriate scientific and ethical standards because of their importance in protecting for Medicare beneficiaries.

The use of standards is essential to protecting Medicare study participants in category A trials. Studies that have high scientific and ethical standards lead to generalizable and reliable knowledge for Medicare providers, practitioners and beneficiaries.

We believe that minimum standards are needed for IDE studies and trials for which Medicare coverage of devices or routine items and services is provided to ensure that Medicare beneficiaries who volunteer to participate in studies are protected and that the study design is appropriate to answer questions of importance to Medicare and its beneficiaries. Although an item or service may be considered ''reasonable and necessary'' when used by a clinician for the benefit of an individual patient, it may not necessarily be reasonable and necessary when used in the context of an IDE study or trial. The use of such an item or service in an IDE study or trial may expose the study participants to increased risks that must be balanced by other factors, including the likelihood that the study would add important information to the body of

medical knowledge. There are numerous studies that may be considered ''scientifically valid,'' but are of little benefit to patients or to the Medicare program.

It is essential that CMS-approved IDE studies or trials serve the best interests of Medicare beneficiaries. We believe, in concert with other federal agencies, that appropriate study design is critical to ensure that not only are participants in research studies exposed to the least risk possible, but also to ensure that the results from the study would be useful in improving healthcare delivery. Scientifically and ethically flawed studies will not produce valid results, exposing Medicare beneficiaries to unnecessary risk; and wasting time and resources for all involved.

We are proposing 13 standards that Category A IDE studies must meet in order for the costs of routine care items and services to be coverable. The first four and the seventh proposed standards embody ethical values. The fifth and sixth proposed standards were developed in response to reports of egregious misconduct in the past in endeavors to conduct clinical research by placing individuals at the risk of harm for the good of others. Both the independent review of protocols and informed consent by study participants are warranted to provide accountability to the public that the conduct of the study is not compromised by potential conflicts of interest on the part of investigators, and the study subject's autonomy is respected.

The IDE study and trial standards that we are proposing are as follows:

- The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of patients who are represented by the Medicare-enrolled subjects.
- The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- The study results are not anticipated to unjustifiably duplicate existing knowledge.
- The study design is methodologically appropriate and the anticipated number of enrolled subjects is appropriate to answer the research question(s) being asked in the study.
- The study is sponsored by an organization or individual capable of completing it successfully.
- The study is in compliance with all applicable federal regulations concerning the protection of human subjects found at 45 CFR part 46.
- All aspects of the study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors.
- The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
- Where appropriate, the clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this standard only if the disease or condition being studied is life threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options.
- The study is registered on the *ClinicalTrials.gov* Web site and/or the Registry of Patient Registries (RoPR) by the principal sponsor/investigator prior to the enrollment of the first study subject.
- The study protocol specifies the method and timing of public release of results on all pre-specified outcomes, including release of negative outcomes. The release should be hastened if the study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (*http://www.icmje.org*). However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.
- The study protocol explicitly discusses subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the study. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- The study protocol explicitly discusses how the results are or are not expected to be generalizable to subsections of the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

In proposed § 405.212(a)(1) through (7), we would set forth scientific standards for IDE studies or trials in which providers, practitioners, suppliers or beneficiaries are requesting payment for items or services provided to Medicare beneficiaries participating in the IDE study or trial.

While most studies are undertaken only after a detailed protocol has been developed, some are not. The protocol is the primary source of knowledge on the proposed design and management of the study. Without this document, reviewers and funding entities are unable to ascertain the quality and validity of the study. The exercise of committing to paper all the aspects of the study is crucial to ensuring that all potential concerns have been addressed. It is impossible to evaluate the adequacy of trial design without a written protocol. We do not propose to define the content of that protocol. Numerous federal agencies and other scientific entities have done that. However, in proposed § 405.212(a)(8) we would specify that all IDE studies or trials must have a written protocol addressing the Medicare standards.

In proposed § 405.212(a)(9), we would specify the ''therapeutic intent'' requirement. We are proposing a standard that limits IDE studies to those that do not exclusively test toxicity or disease pathophysiology in healthy individuals but also have a therapeutic outcome. However, the study may exclusively test toxicity or disease pathophysiology, if the disease or condition being studied must be life-threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options or is severely debilitating as defined in 21 CFR 312.81(b). In proposed § 405.212(a)(10), we would specify the standard that requires that IDE studies and trials that Medicare supports be registered on *ClinicalTrials.gov site*. The National Institutes of Health/National Library of Medicine (NIH/NLM) established a clinical trials registry (*ClinicalTrials.gov*) to meet the requirement of the 1997 Food and Drug Administration Modernization Act. After a thorough review of the NIH/NLM *ClinicalTrials.gov* Web site, we believe that all studies covered under this policy should be registered in this registry prior to enrollment of the first subject.

Registration into *ClinicalTrials.gov* assures that beneficiaries would have pertinent information about and IDE study or trial Medicare supports—an essential component of transparency to

facilitate patient-provider informed decision-making. The World Health Organization and International Committee of Medical Journal Editors (WHO/ICMJE) data elements are the required data elements in this registry. Information about this registry may be obtained at *http://www.clinicaltrials.gov/*. We believe that registration serves the public's desire to obtain information about the studies that their Medicare premiums and tax dollars support.

In proposed § 405.212(a)(11), we would address the issue of dissemination of the IDE study or trial findings. We believe that it is imperative that the results of IDE studies and trials for which Medicare has made payment of any clinical costs be made available to the public regardless of the outcomes. If trial results are not published, they do not add to the clinical evidence base and cannot be used for medical decision-making. For this standard, we are suggesting that the study protocol provides a discussion of the publication/dissemination plan of the study findings.

In proposed § 405.212(a)(12), we would focus on the issue of under-representation of specific demographic groups in U.S. clinical research studies. We want to support studies that allow Medicare beneficiaries to voluntarily participate in; and that add to the knowledge base about the use of the IDE device in the Medicare population, to ultimately improve the quality of care that Medicare beneficiaries receive. Well-designed studies have protocols that define the populations with the highest risk of having the disease or condition being studied. If data are not available that clearly demonstrate differences of clinical importance in subgroups defined by gender, race/ethnicity, age, or other relevant subpopulations, then the protocol must discuss the necessary steps to enroll appropriate numbers of these populations to ensure a valid analysis of the intervention effects. It is not our intention to require a specific enrollment of all subpopulations. However, it is, our intention that all covered study protocols address populations affected by the technology under investigation with special emphasis on minority and other groups that have experienced disparities in health care due to a lack of quality research data. If convincing evidence indicates that no differences exist between identified subgroups, that information should be noted in the protocol.

In proposed § 405.212(a)(13), we would specify the standard that requires that an IDE study or trial protocol explicitly discuss how the results are or are not expected to be generalizable to subsections of the Medicare population and to infer whether Medicare patients may benefit from the intervention. More often than not the published evidence does not include the Medicare population. We believe that unless there are clear data documenting that no important differences exist between the Medicare beneficiaries and the population studied, the study must discuss the enrollment of appropriate numbers representative of the Medicare population to ensure that the analysis of the results of the intervention may be applicable to Medicare beneficiaries.

In § 405.211, we are proposing that if the following two characteristics are also included met in addition to the criteria listed in § 405.212(a)(1) through (a)(13), we would automatically cover the costs of routine items and services in the Category A study or trial, and the costs of the investigation device and the routine items and services in a Category B study or trial as follows:

- The study is a pivotal study.
- The study has is a superiority study design.

In § 405.212, we propose a process by which Category A IDE studies will qualify for Medicare coverage of routine items and services provided in the studies. We propose that any interested party who seeks coverage in an IDE study may send us a request letter that describes the scope and nature of the IDE study, discussing each of the 15 standards in this policy.

b. Category B IDE Devices

Under our regulations, a nonexperimental/investigational (Category B) device was described as a device for which the underlying questions of safety and effectiveness has been resolved. In the absence of a NCD, Medicare coverage for Category B devices has been decided by Medicare contractors, subject to review under the claims review process at § 405.211(b). If the Category B device was covered, Medicare also covered the costs of items and services specific to the use of the device and furnished in conjunction with an FDA-approved clinical study.

Beyond Category A IDE studies, we believe that all investigational device studies wherein Medicare coverage is sought should conform to rigorous scientific and ethical standards. We believe that regardless of whether the device is categorized as an A or B the IDE study should meet the same scientific and ethical standards. Thus, we are proposing to require that Category B IDE trials must meet the same scientific and ethical standards.

c. Review and Approval (§ 405.212)

We are proposing a centralized IDE coverage review process for Category A and Category B IDEs. We believe the criteria § 405.212(a)(1) through (a)(13) are integral to coverage in any study that is Medicare-approved because it ensures that the IDE device is being furnished in a study with high levels of scientific and ethical integrity.

In addition, we propose to cover Category B IDE devices and the costs of routine care items and services furnished in an IDE study that meets the criteria proposed § 405.212(a) and the following additional criteria:

- The study is a pivotal study.
- The study has is a superiority study design.

As we review the IDE studies, we would look for reasonable assurance that enrolled Medicare beneficiary subjects will receive the best possible care and are protected when they are subjects in these IDE studies. The pivotal study and superiority study design criteria furnish assurances that the study results will be informative for beneficiary choices and medical decision-making in the non-trial settings where most care is actually furnished. We believe that their decisions are facilitated by trial designs that allow them to compare their options and determine which one is superior for the beneficiary. Non-inferiority trial designs (in contrast to superiority designs) only support more limited and thus less useful conclusions, that is, that the investigated device is no worse than the comparator treatment by some pre-specified margin.

Supporting materials may be submitted. The request would include the following information:

- The FDA approval letter.
- IDE study protocol.
- IRB approval letter(s).
- The *ClinicalTrials.gov* identifier

We propose that requests should be submitted via email to *clinicalstudynotification@cms.hhs.gov* or via hard copy to the following address:

Centers for Medicare & Medicaid Services, Center for Clinical Standards & Quality, Director, Coverage and Analysis Group, ATTN: Clinical Study Certification, Mailstop: S1–02–01, 7500 Security Blvd., Baltimore, MD 21244.

d. Notification

We propose that we would notify beneficiaries, providers, and practitioners of the IDE studies of all IDE devices eligible for coverage by

posting the IDE study title and *ClinicalTrials.gov* registry number on our Web site and publishing a list in the **Federal Register**.

e. Additional/Conforming Changes

In addition to the proposed changes in § 405.211 and § 405.212, we note the following changes:

• In § 405.201(b), Definitions, we would be revised the section by removing, revising and adding definitions. Some of the definitions that we are proposing to remove comprise factors that will allow stakeholders to understand the clinical study criteria for items and services furnished in an IDE study including the Category A and B device itself. Therefore, we proposing the following changes

++ Removal of the following definitions:

++ Class I, II, and III devices which refers to the different designations of FDA devices. These designations are not relevant to CMS coverage of an IDE device and routine items and services in an IDE study.

++ Post-market approval refers to a marketing application for a Class III device. Like class this is not relevant to whether CMS may cover an IDE device or routine items or services in an IDE study.

++ Adding the following definitions:

—*Clinicaltrials.gov* which refers to the National Institutes of Health's National Library of Medicine's online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. After a thorough review of the NIH/NLM *ClinicalTrials.gov* Web site, we believe that all studies covered under this policy should be registered in this registry. This is common practice in the research community. Studies and trials are now transparent—the study sites, investigator names, source of support, description of the study methods, and study results are open to the public, including Medicare beneficiaries. We believe that registration serves the public's desire to obtain information about the studies they may want to participate. This is a benefit to beneficiaries and their providers participating in IDE studies.

—Pivotal studies or trials, which refer to clinical investigations designed to collect definitive evidence of the safety and effectiveness of a device for a specified intended use, typically in a statistically justified number of subjects. It may or may not be preceded by an early and/or a traditional feasibility study or trial.

—Routine care items and services, which refer to items and services that are otherwise generally available to Medicare beneficiaries (that is, there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are furnished in either the experimental or the control arms of a clinical trial and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical trial. We note that noncoverage of a routine care item or services under an IDE trial in no way restricts a beneficiary's access to guaranteed Medicare benefits outside of an IDE trial.

—Superiority studies refer to studies or trials that are intended to demonstrate at some pre-specified level of confidence that the effect of an investigational treatment is superior to that of an active control by more than a pre-specified margin.

We are proposing the additions of the previously discussed definitions because we would use these factors in our decision to cover an investigational device and the costs of routine items and services in an IDE study.

• We are proposing to modify the following definitions:

++ The term Category A which was developed in cooperation with the FDA for the purposes of distinguishing those FDA classes under which investigational and non-investigational devices fall. A Category A IDE device is considered an experimental device; and therefore, deemed noncovered by Medicare standards.

++ Category A device would be defined as a device for which ''absolute risk'' of the device type has not been established (that is, the question of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

++ The term Category B which was developed in cooperation with the FDA for the purposes of distinguishing those FDA classes under which investigational and non-investigational devices fall. FDA assigns each device with an FDA-approved IDE to one of two categories. We propose to revise the definition of Category B (Nonexperimental/investigational) device to mean a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

++ Contractors mean Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare items and services. Currently, this is the definition refers to CMS's local Medicare Contractors. We propose to update the current definition in order for the definition to be accurate and consistent Agency-wide.

++ *IDE stands for investigational device exemption.* An FDA-approved IDE application permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

In § 405.203, FDA categorization of investigational devices, we are not proposing any changes. We have found that the interagency agreement between the FDA and CMS that supports the FDA categorization of devices to one of two categories for investigational purpose is widely accepted among device manufacturers. Therefore, to avoid future confusion by changing the categorization, we believe that maintaining this process continues to support the development of new health technologies and tools that practitioners and beneficiaries have access. It should be noted that neither the determination nor any re-evaluation made by FDA, nor the review determination made by CMS under § 405.211, would be considered coverage determinations that implicate the Part 426 NCD/LCD appeals process.

In § 405.207—

• In paragraph (a), we are not proposing any changes to our current noncoverage of Category A IDE devices. As stated previously, we continue to find that because initial questions of safety and effectiveness have not been resolved and the FDA is unsure of whether the device type can be safe and effective, experimental/investigational (Category A) devices are not reasonable and necessary under section 1862(a)(1)(A) of the Act; and

• Paragraph (b) currently states that all Category A IDE studies and trials must meet the criteria established through the NCD process. Because we are proposing scientific and ethical standards, we no longer need to establish the IDE study criteria through the NCD process; and therefore, we are proposing to delete the NCD process requirement. We are also proposing to remove the following statement from § 405.207(b)(2) that states ''If the trial is initiated before January 1, 2010, the device must be determined as intended for use in the diagnosis, monitoring or treatment of an immediately life-

threatening disease or condition'' because it is no longer applicable. We are not proposing changes to § 405.207(b)(1) or (b)(3).

In §§ 405.205, 405.207, 405.209, and 405.211, we propose to retain the current explanation of coverage and payment for non-experimental/investigational devices.

For § 405.213, Re-evaluation of a device categorization, we are not proposing any changes to this section because we believe that maintaining this process continues to support the development of new health technologies and tools that practitioners and beneficiaries have access.

We are proposing to retain the protections in § 405.215, Confidential Commercial and Trade Secret Information, without modification. We note that section 502(c) of the Act broadly prohibits the disclosure of trade secret and confidential commercial or financial information—information exempt from public disclosure by the Freedom of Information Act (FOIA) 5 U.S.C. 552(b)(4) outside the Department. This prohibition is found in the devices and regulatory inspections provisions of the Act, and is not limited to device-related information. This disclosure prohibition also applies to information reported or otherwise obtained by the Department during inspection activities and other activities. This prohibition is interpreted to allow information sharing within the U.S. Department of Health and Human Services only.

In § 411.15(o)(2), Experimental or investigational device exclusions, we propose to revise the requirement to specify that the exclusions under this section include experimental or investigational devices, except for certain devices furnished in accordance with the CMS IDE study and trial standards established in § 405.21l. We are proposing this change to be consistent with the IDE study characteristics.

B. Ultrasound Screening for Abdominal Aortic Aneurysms

1. Background and Statutory Authority

Section 1861(s)(2)(AA) of the Act authorizes Medicare coverage under Part B of ultrasound screening for abdominal aortic aneurysms (''AAA screening''), as defined in section 1861(bbb) of the Act. Our implementing regulations for AAA screening are at § 410.19. AAA screening is covered for a beneficiary that meets certain criteria including that he or she must receive a referral during the initial preventive physical examination (IPPE) and has not previously had an AAA screening covered under the Medicare program. The IPPE, as described in section 1861(ww) of the Act (and regulations at § 410.16), includes a time restriction and must be furnished not more than one year after the effective date of the beneficiary's first Part B coverage period (see section 1862(a)(1)(K) of the Act). This time limitation for the IPPE effectively reduces a Medicare beneficiary's ability to obtain a referral for AAA screening.

Section 1834(n) of the Act, added by section 4105 of the Affordable Care Act, grants the Secretary the discretion and authority to modify coverage of certain preventive services identified in section 1861(ddd)(3) of the Act, which in turn cross-references section 1861(ww)(2) of the Act (including AAA screening at section 1861(ww)(2)(L). The Secretary may modify coverage to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force (USPSTF) per section 1834(n)(1)(A) of the Act. In 2005, the USPSTF recommended ''one-time screening for [AAA] by ultrasonography in men ages 65 through 75 who have ever smoked. (Grade: B Recommendation)'' (Screening for Abdominal Aortic Aneurysm: Recommendation Statement. *http://www.uspreventiveservicestaskforce.org/uspstf05/aaascr/aaars.htm*). The USPSTF recommendation does not include a time limit with respect to the referral for this test.

2. Provisions of the Proposed Regulations

We are proposing to exercise our discretion and authority under section 1834(n) of the Act to modify coverage of AAA screening consistent with the recommendations of the USPSTF to eliminate the one-year time limit with respect to the referral for this service. This proposed modification would allow coverage of AAA screening for eligible beneficiaries without requiring them to receive a referral as part of the IPPE. Specifically for purposes of coverage of AAA screening, we propose to modify the definition of ''eligible beneficiary'' in § 410.19(a) by removing paragraph (a)(1), of this definition, and redesignating paragraphs (a)(2) and (a)(3) of this definition as paragraphs (a)(1) and (a)(2), respectively.

The IPPE is a one-time benefit available to beneficiaries under Part B that receive the IPPE not more than one year after the effective date of the beneficiary's first Medicare Part B coverage period. Many beneficiaries were either not eligible to receive an IPPE (which did not become effective until January 1, 2005) or may not have taken advantage of the IPPE when they were eligible, limiting access to AAA screening. We believe that our proposed modification is consistent with current USPSTF recommendations for one-time screening and allows for expanded access to this important preventive service. We invite public comment on this proposal.

C. Colorectal Cancer Screening: Modification to Coverage of Screening Fecal Occult Blood Tests

1. Background and Statutory Authority

Sections 1861(s)(2)(R) and 1861(pp)(1) of the Act authorize Medicare coverage of colorectal cancer screening. The statute authorizes coverage of screening fecal occult blood tests (FOBT), screening flexible sigmoidoscopies, screening colonoscopies, and other tests determined to be appropriate, subject to certain frequency and payment limits. Section 410.37(b) (condition for coverage of screening FOBT) specifies that Medicare Part B pays for screening FOBT if ordered in writing by the beneficiary's attending physician. For purposes of § 410.37, ''attending physician'' is defined as ''a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible using the results of any examination performed in the overall management of the beneficiary's specific medical problem.''

The coverage provisions for FOBT screening were established in 1997 and effective on January 1, 1998 (62 FR 59048, October 31, 1997). In the preamble to that final rule, we stated that the requirement for a written order from the attending physician was intended to make certain that beneficiaries receive appropriate preventive counseling about the implications and possible results of having these examinations performed (62 FR 59081).

Since then, Medicare coverage of preventive services has expanded to include, among other things, coverage of an annual wellness visit (as defined in § 410.15). The annual wellness visit includes provisions for furnishing personalized health advice and appropriate referrals. In addition to physicians, the annual wellness visit can be furnished by certain nonphysician practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists.

Additionally, § 410.32 provides coverage and payment rules for diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic

tests. Section 410.32(a)(2) states: ''Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.''

2. Proposed Revisions

We are proposing to revise § 410.37(b), ''Condition for coverage of screening fecal-occult blood tests,'' to allow an attending physician, physician assistant, nurse practitioner, or clinical nurse specialist to furnish written orders for screening FOBT. These proposed modifications would allow for expanded coverage and access to screening FOBT, particularly in rural areas. We invite public comment on this proposal. In addition, we are seeking public comment regarding whether a practitioner permitted to order a screening FOBT must be the beneficiary's attending practitioner as described earlier.

D. Ambulance Fee Schedule

1. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, enacted on July 15, 2008) (MIPPA) amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

Sections 3105(a) and 10311(a) of the Affordable Care Act further amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2010, and before January 1, 2011. In the CY 2011 PFS final rule with comment period (75 FR 73385, 73386, 73625), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Section 106(a) of the Medicare and Medicaid Extenders Act of 2010 (Pub. L.111–309, enacted December 15, 2010) (MMEA) again amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2011, and before January 1, 2012. In the CY 2012 End-Stage Renal Disease Prospective Payment System (ESRD PPS) final rule (76 FR 70228, 70284 through 70285, and 70315), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Section 306(a) of the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCA) (Pub. L. 112–78, enacted on December 23, 2011) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through February 29, 2012; and section 3007(a) of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, enacted on February 22, 2012) (MCTRJCA) further amended section 1834(l)(13)(A) of the Act to extend these payment add-ons through December 31, 2012. Thus, these payment add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2012 and before January 1, 2013. In the CY 2013 PFS final rule (77 FR 69139, 69368), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Subsequently, section 604(a) of the ATRA amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through December 31, 2013. Thus, these payment add-ons also apply to covered ground ambulance transports furnished on or after January 1, 2013 and before January 1, 2014. Thus, we propose to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

2. Amendment to Section 146(b)(1) of MIPPA

Section 146(b)(1) of the MIPPA amended the designation of certain rural areas for payment of air ambulance services. This section originally specified that any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must continue to be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2009.

Sections 3105(b) and 10311(b) of the Affordable Care Act amended section 146(b)(1) of MIPPA to extend this provision for an additional year, through December 31, 2010. In the CY 2011 PFS final rule (75 FR 73385, 73386, and 73625 through 73626), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Section 106(b) of the MMEA amended section 146(b)(1) of MIPPA to extend this provision again through December 31, 2011. In the CY 2012 ESRD PPS final rule (76 FR 70284, 70285, and 70315), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Subsequently, section 306(b) of the TPTCCA amended section 146(b)(1) of MIPPA to extend this provision through February 29, 2012; and section 3007(b) of the MCTRJCA further amended section 146(b)(1) of MIPPA to extend this provision through December 31, 2012. In the CY 2013 PFS final rule (77 FR 69139, 69140, and 69368), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Subsequently, section 604(b) of the ATRA amended section 146(b)(1) of MIPPA to extend this provision through June 30, 2013. Thus, we propose to revise § 414.610(h) to conform the regulations to this statutory requirement.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of a rural indicator, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for areas that were designated as rural on December 31, 2006, and were subsequently re-designated as urban, we have re-established the ''rural'' indicator on the ZIP Code file for air ambulance services through June 30, 2013.

3. Amendment to Section 1834(l)(12) of the Act

Section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–

173, enacted on December 8, 2003) (MMA) added section 1834(l)(12) to the Act, which specified that in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area''; that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract).

Sections 3105(c) and 10311(c) of the Affordable Care Act amended section 1834(l)(12)(A) of the Act to extend this rural bonus for an additional year through December 31, 2010. In the CY 2011 PFS final rule with comment period (75 FR 73385, 73386 and 73625), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 106(c) of the MMEA amended section 1834(l)(12)(A) of the Act to extend the rural bonus described above for an additional year, through December 31, 2011. Therefore, in the CY 2012 ESRD PPS final rule (76 FR 70284, 70285 and 70315), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 306(c) of the TPTCCA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through February 29, 2012; and section 3007(c) of the MCTRJCA further amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2012. In the CY 2013 PFS final rule with comment period (77 FR 69140, 69368), we revised § 414.610(c)(5)(ii) to conform the regulations to these statutory requirements.

Subsequently, section 604(c) of the ATRA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2013. Therefore, we are continuing to apply the 22.6 percent rural bonus described above (in the same manner as in previous years), to ground ambulance services with dates of service on or after January 1, 2013 and before January 1, 2014 where transportation originates in a qualified rural area. Accordingly, we propose to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims adjudicative process via the use of a data field included on the CMS-supplied ZIP Code File.

This statutory requirement is self-implementing. This provision requires a one-year extension of the rural bonus (which was previously established by the Secretary) through December 31, 2013, and does not require any substantive exercise of discretion on the part of the Secretary.

4. Addition of Section 1834(l)(15) of the Act

Section 637 of the ATRA, which added section 1834(l)(15) of the Act, specifies that the fee schedule amount otherwise applicable under the preceding provisions of section 1834(l) of the Act shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility. We are proposing to revise § 414.610 by adding paragraph (c)(8) to conform the regulations to this statutory requirement.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate decrease, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for the ambulance services described in section 637 of the ATRA furnished on or after October 1, 2013, the fee schedule amount otherwise applicable (both base rate and mileage) will be reduced by 10 percent. For further information regarding application of this mandated rate decrease, please see CR 8269.

5. Studies of Ambulance Costs

Section 604(d)(1) of the ATRA provides that the Secretary shall conduct the following studies:

(A) A study that analyzes data on existing cost reports for ambulance services furnished by hospitals and critical access hospitals, including variation by characteristics of such providers of services, with a Report to Congress on such study due no later than October 1, 2013; and

(B) A study of the feasibility of obtaining cost data on a periodic basis from all ambulance providers of services and suppliers for potential use in examining the appropriateness of the Medicare add-on payments for ground ambulance services furnished under the fee schedule under section 1834(l) of the Act and in preparing for future reform of such payment system, with a Report to Congress due on such study no later than July 1, 2014.

Further, in conducting the study under paragraph (B) above, section 604(d)(2) of the ATRA directs the Secretary to:

- Consult with industry on the design of such cost collection efforts;
- Explore the use of cost surveys and cost reports to collect appropriate cost data and the periodicity of such cost data collection;
- Examine the feasibility of developing a standard cost reporting tool for providers of services and suppliers of ground ambulance services; and
- Examine the ability to furnish such cost data by various types of ambulance providers of services and suppliers, especially by rural and super-rural providers of services and suppliers.

As noted above, in conducting the study under section 604(d)(1) of the ATRA described in paragraph (B) above, the Secretary is required to consult with industry on the design of such cost collection efforts (see section 604(d)(2)(A) of the ATRA). We are using this proposed rule as the instrument to collect information, comments, and ideas from the industry on the design of such cost collection efforts as described above, and on the feasibility of obtaining cost data on a periodic basis from all ambulance providers of services and suppliers for potential use in examining the appropriateness of the Medicare add-on payments for ground ambulance services furnished under the fee schedule under section 1834(l) of the Act and in preparing for future reform of such payment system. We therefore invite public comment on these issues

as part of the study we are conducting under section 604(d)(1)(B) of the ATRA.

E. Proposals Regarding the Clinical Laboratory Fee Schedule

1. Background on the Clinical Laboratory Fee Schedule

Under Medicare Part B, clinical diagnostic laboratory tests furnished on or after July 1, 1984, in a physician's office, by an independent laboratory, or by a hospital laboratory for its outpatients and nonpatients currently are paid on the basis of the Clinical Laboratory Fee Schedule (CLFS), with limited exceptions. For each Healthcare Common Procedure Coding System (HCPCS) code, payment is the lesser of:

- The amount of charges billed for the test;
- The fee schedule amount for the State or a local geographic area; or
- A national limitation amount (NLA) (section 1833(a)(1)(D)(i), (a)(2)(D)(i), (h)(1), and (h)(4)(B) of the Act). The NLA for a clinical diagnostic laboratory test performed after December 31, 1997 is equal to 74 percent of the median of all fee schedules established for that test for that laboratory setting or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established (section 1833(h)(4)(B)(viii) of the Act).

Currently, we update the CLFS amounts annually to reflect changes in the Consumer Price Index for all Urban Consumers (U.S. city average) (CPI–U) and apply a multi-factor productivity adjustment (see section 1833(h)(2)(A) of the Act). In the past, we also implemented other adjustments or did not apply the change in the CPI–U to the CLFS in accordance with statutory mandates. For example, under section 1833(h)(2)(A)(i) of the Act, we were required to subtract 0.5 percentage points from the CPI–U adjustment for 2009 and 2010. We do not otherwise update or change the CLFS.

For any clinical diagnostic laboratory tests where a new or substantially revised HCPCS code is assigned on or after January 1, 2005, we determine the basis for, and amount of, payment for these clinical diagnostic laboratory tests (see section 1833(h)(8) of the Act and 42 CFR 414.500 through 414.509). Once established, however, in most cases, we only have the opportunity to reconsider the basis and/or amount of payment for new tests for one additional year after the basis or payment is initially set. Once the reconsideration process is complete, payment is not further adjusted (except by a change in the CPI–U, the productivity adjustment, and any other adjustments required by statute), regardless of any shift in the actual costs incurred to perform the test.

This lack of an established mechanism to adjust payment amounts is unique among the Medicare payment schedules and systems. Generally, fee schedules and prospective payment systems are evaluated each year to reflect the changing mix of services provided under that system or schedule and then the system or schedule is adjusted to maintain budget neutrality. Since there is currently no process to make such adjustments for the CLFS, payment amounts are essentially locked in place and do not change when the cost of the test changes. As discussed below, in this proposed rule, we are proposing to implement a process to adjust payment amounts based on changes in technology.

2. Proposals Regarding Technological Changes Under Section 1833(h)(2)(A)(i) of the Act

a. Background on Technological Changes

There has been a significant amount of technological change in the clinical laboratory area since the implementation of the CLFS, which has resulted in the increased use of point-of-care testing, brand new tests being developed, and the proliferation of laboratory-developed tests. The Institute of Medicine (IOM) dedicated a chapter of its 2000 report ''Medicare Laboratory Payment Policy: Now and in the Future'' to discussing trends in laboratory technology. The report noted rapid and dramatic innovation in the laboratory sector since the 1980s and remarkable growth in the range and complexity of available tests. The IOM concluded that the introduction of new tests, advances in equipment and testing techniques, and the proliferation of advanced information technology have all made testing more efficient and automated.

Technology has enabled a significant site-of-service shift for many laboratory tests from the laboratory environment to the point of health care delivery. This point-of-care testing has increased since the 1980s, when this type of testing first became available, mainly due to changes in technology which resulted in smaller, cheaper, and more portable test kits that are simple to use. For example, drug abuse testing has become readily available at the point of care. Point-of-care testing can be performed in various institutional and community settings but the main objective of such testing is to produce a result quickly, at the place where the patient is receiving care, such as at a physician's office or at a hospital bedside, to facilitate decisions about appropriate treatment.

There are also brand new technologies that did not exist when the CLFS was established, most notably genetic and genomic tests. This area of medicine evolved from the work of the Human Genome Project and subsequent research and development by both the federal government and private firms. The cost of sequencing a genome has dropped dramatically since the early inception of this technology in 2001 from more than $95 million per genome to approximately $5,700 in early 2013 (*http://www.genome.gov/pages/der/sequencing_cost.xlsx*). Early tests in this area were less likely to be covered by Medicare because they were either screening tests or tests for conditions found in the pediatric population. As this area has expanded over the past several decades, Medicare has taken on a more prominent role in payment for these services (see 77 FR 68994 through 69002 for a thorough discussion of how Medicare pays for these tests). We expect the number of codes and tests in this area to continue to grow as the technology evolves and more tests become available in the areas of pharmacogenomics, personalized and predictive medicine, and companion diagnostics.

We also note the growth in laboratory-developed tests (LDTs) over the years. These proprietary tests are developed by laboratories, which then offer the service of providing the test. Some of the most advanced laboratory tests currently being performed are LDTs which use sophisticated proprietary technology. Many LDTs do not have their own codes; instead, they are billed using unlisted codes for which contractors establish a payment amount. Other LDTs were billed to Medicare using ''stacking codes,'' where a laboratory submits a code for each step of the testing process; however, these ''stacking codes'' were eliminated at the end of 2012 for molecular pathology tests and replaced with 114 new test-specific codes. These payment processes provide us with limited information about the technology used to perform these tests. However, we know that the number of LDTs has been growing over the years and multiple laboratories have developed ways to perform the same test. Further, our recent experience with using a gap filling methodology to price molecular pathology tests, which are often LDTs, has shown that the costs of performing these tests have decreased since contractors initially established

payment amounts for the tests, or compared to the code stack previously billed. Our experience with gap filling molecular pathology tests has also shown that there is wide variation in the cost of performing the same test by different laboratories.

We believe that, given the technological changes that have occurred in the laboratory industry over the past several decades and the growth in the number of clinical laboratory tests (CMS has added approximately 800 new test codes to the CLFS since its inception), it would be appropriate to establish a process to reconsider payment amounts on the CLFS to take into account increased efficiency, changes in laboratory personnel and supplies necessary to conduct a test, changes in sites of service, and other changes driven by technological advances.

Section 1833(h)(2)(A)(i) of the Act requires the Secretary to set the fee schedules for clinical laboratory tests ''for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to [the multi-factor productivity adjustment], [the change in the CPI–U] and *subject to such other adjustments as the Secretary determines are justified by technological changes''* (emphasis added). Under this authority, we are proposing a process under which we will systematically reexamine the payment amounts established under the CLFS to determine if changes in technology for the delivery of that service warrant an adjustment to the payment amount.

b. Proposed Definition of Technological Changes

We are proposing to define technological changes as changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used. Changes in technology could result in changes to, among other things, the resources required to perform the test (such as the type, volume, or number of supplies or reagents required), the laboratory personnel required to perform the test, and/or the frequency of testing, volume of testing, or site of service (for example, a shift in service site from a specialty laboratory to a physician's office). We believe this broad definition would capture all of the technological changes that could impact the resource inputs for various tests on the CLFS. As discussed below, the technological changes for a specific test would be discussed in the proposed rule in which we are proposing to adjust the payment amount for that test, and we would seek public comment on our determination of the technological changes and the payment adjustment.

c. Proposed Process

We are proposing that, each year, we would review certain codes on the CLFS, as described in the next section, to determine whether we believe that payment for these codes should be adjusted due to technological changes. For those codes where we determine that payment adjustments should be made, beginning with the CY 2015 PFS proposed rule, we would identify the test code, discuss how it has been impacted by technological changes, and propose an associated adjustment to the payment amount for the test code as appropriate to reflect the impact of such technological changes.

We believe such adjustments could be made both to increase fee schedule amounts (for example, in situations where new high cost technologies are employed), and to provide for reductions in existing amounts (for example in situations where technology reduces costs through increased efficiencies). We expect that most payment amounts will decrease due to the changes in technology that have occurred over the years since the payment amounts were established and the general downward trend of costs once technology has had an opportunity to diffuse. A key goal in establishing this review process is to ensure payment accuracy after technological changes; thus payment rates could increase or decrease as a result of these reviews.

Under our proposed process, we would also list codes that we reviewed but for which there was insufficient information to support or establish an adjustment to the payment amount due to technological changes. We would solicit comment on the technology used to perform any tests we reviewed for possible payment changes, and any relevant cost information. We expect that we would finalize any payment adjustments in the PFS final rule, beginning with the CY 2015 PFS final rule. We are proposing that the CPI–U and multi-factor productivity adjustments would be applied after we establish the new payment amount through our usual instruction process.

We believe that this proposed process would best allow for the greatest amount of transparency in review and the most structured and consistent opportunity for the public to provide input into the process. We are soliciting comment on these proposals.

d. Proposed Identification and Prioritization of Codes to be Reviewed

We are proposing to review all codes currently on the CLFS. We are proposing to start our review by examining the codes that have been on the CLFS the longest and then work our way forward, over multiple years, until we have reviewed all of the codes on the CLFS. We believe that the payment amounts for codes that have been on the CLFS the longest amount of time would be most affected by changes in technology because, in general, technology is most expensive earliest in its life cycle but decreases in cost as the technology matures and diffuses. If during the course of reviewing these individual codes we find that there are additional, newer codes that are clinically and/or technologically similar, we are proposing to consider them for review at the same time as we review the older codes because we expect we would have the same or similar justifications for making payment adjustments to those codes. We intend to review these codes as quickly as possible but we believe there would be a significant administrative burden associated with such a comprehensive review of the 1,250 codes on the CLFS. We are estimating that it would take at least 5 years to review all of the existing codes on the CLFS.

Once we have completed our review of the codes currently on the CLFS and made any adjustments necessary due to technological changes, we are proposing to review codes added to the CLFS after 2015 that have been on the CLFS for at least 5 years. We would also review codes again that have not been reviewed in the previous 5 years, as time and resources allow. We believe that tests that are less than 5 years old are likely still in their technological infancy and enough time would not have passed to adequately assess any change in technology for those services. Similarly, for previously reviewed codes, we believe that technology likely would not have changed dramatically in less than 5 years. We are soliciting public comment on how to prioritize these codes, which we expect to address in future rulemaking on this issue.

After the initial review of the codes currently on the CLFS, we are also proposing to allow the public to nominate additional codes for review, including those that had been previously reviewed for technological change. We are proposing that the public may nominate only codes that have been on the CLFS for at least 5 years and that have not been reviewed in the previous 5 years. Further, we are

proposing that the nomination must include an explanation from the nominator of the technological change in the service and the way that change affects its delivery. We would then consider these nominations and, in the **Federal Register** the following year, either propose a payment change based on technological changes or explain why we think such a change is not warranted at that time.

We are proposing to codify the proposed process at 42 CFR 414.511.

We are seeking public comment on these proposals. We also are seeking comment on alternative approaches to achieving our goal of paying appropriately for laboratory tests by accounting for changes in technology. Finally, we are soliciting comment on general trends in technology change in the laboratory industry and the health care sector in general.

3. Proposed Changes in the CY 2014 OPPS/ASC Proposed Rule

In the CY 2014 OPPS/ASC proposed rule, CMS is proposing to package payment for certain clinical diagnostic laboratory tests into the base payment for the Ambulatory Payment Classification (APC). For details on this proposal, please see the ''Proposed Changes to Packaged Items and Services'' section of the CY 2014 OPPS/ASC proposed rule. Comments on the OPPS proposal should be made to the CY 2014 OPPS/ASC proposed rule. Comments on the proposals in this rule should be made to the CY 2014 PFS proposed rule.

F. Liability for Overpayments to or on Behalf of Individuals Including Payments to Providers or Other Persons

1. Background and Statutory Authority

CMS waives recovery of overpayments in certain situations for claims based fee-for-service provider, supplier or beneficiary overpayments in accordance with section 1870 of the Act. Section 1870(b) and (c) of the Act provide a waiver of recovery of provider, supplier or beneficiary overpayments under certain presumptions within a specified timeframe. Section 1870(b) and (c) of the Act allow the Secretary to reduce the specified time period to not less than one year if the Secretary finds that such a reduction is consistent with the objectives of the Medicare program. Section 638 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted January 2, 2013) changed the timeframes associated with section 1870(b) and (c) of the Act.

Section 1870(b) of the Act provides for the waiver of recovery of an overpayment to a provider of services (hereinafter, ''provider'') or other person whenever that provider or other person is ''without fault'' in incurring the overpayment. For purposes of section 1870 of the Act and this proposed rule, the term ''other person'' includes practitioners, physicians, and other suppliers.

Section 1870(b) of the Act also establishes circumstances under which a provider or other person is presumed for administrative purposes to be ''without fault'' for an overpayment. If an overpayment is determined after a specified period of time, a provider or other person is presumed to be ''without fault.'' This presumption is negated, however, if there is evidence to show that the provider or other person was responsible for causing the overpayment.

Section 1870(c) of the Act provides for the waiver of recovery of an overpayment to an individual whenever the individual is ''without fault'' in incurring the overpayment, and recovery would either defeat the purpose of the Social Security or Medicare programs or would be ''against equity and good conscience.''

Section 1870(c) of the Act also establishes circumstances under which recovery of an overpayment for an individual is presumed to be ''against equity and good conscience.'' After a specified period of time, recovery of certain overpayments from individuals who are ''without fault'' is presumed ''against equity and good conscience.'' The overpayments addressed by this provision are payments for items or services for which payment may not be made because of the prohibitions found in section 1862(a)(1) or (a)(9) of the Act. Sections 1862(a)(1) and (a)(9) prohibit payment for, among other things, items and services that are not reasonable and necessary or that are for custodial care.

Section 638 of the ATRA amended the timeframe specified in section 1870(b) of the Act ''without fault'' presumption from 3 to 5 years so that the presumption of ''without fault'' only applies if the Medicare claims based fee-for-service overpayment determination for a provider or other person is made subsequent to the fifth year (instead of the third year) following the year in which the notice was sent to such individual that such amount had been paid. Likewise, section 638 of the ATRA amended the timeframe in section 1870(c) of the Act so that the presumption for ''against equity and good conscience'' for certain types of denials for an individual who is ''without fault'' only applies if the overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which notice of such payment was sent to such individual.

These ATRA changes do not affect or change CMS' claims reopening regulation at § 405.980. Specifically, we retain our authority to reopen claims for any reason within one year, for good cause within 4 years, and at any time for fraud or similar fault.

2. Provisions of the Proposed Regulations

We propose to revise § 405.350(c) and § 405.355(b). These proposed revisions would change the timing of the triggering event for the ''without fault'' and ''against equity and good conscience'' presumptions. These revisions are being proposed to reflect the revisions to section 1870 of the Act as specified in by section 638 of ATRA.

Specifically, we propose to change the timeframe at § 405.350(c) so that the rebuttable ''without fault'' presumption for the provider or other person would apply if the Medicare claims based fee-for-service overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which the notice was sent to such individual that such amount had been paid.

Likewise, we propose to amend the timeframe at § 405.355(b) for the presumption ''against equity and good conscience'' for certain types of denials for an individual who is ''without fault'' so that the presumption would apply if the overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which the notice of payment was sent to the individual.

Additionally, in our review of the current regulation implementing section 1870(c) of the Act, we noted that § 405.355(b) does not clearly reflect the statutory language, which limits the ''against equity and good conscience'' presumption to overpayments associated with denials under section 1862(a)(1) or (a)(9) of the Act. Accordingly, we propose to update and clarify § 405.355(b) so that it clearly reflects the statutory language by adding that the ''against equity and good conscience'' presumption would be applicable for an individual who is ''without fault'' only if the overpayment is related to items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act. In addition, we propose to delete the parenthetical at the end of § 405.355(b) because the regulations referenced no longer exists; those

sections of the regulations were reassigned. (See the October 11, 1989 **FEDERAL REGISTER** (54 FR 41733).) The modifications we propose to § 405.355(b) makes the references in the parenthetical no longer necessary.

G. Physician Compare Web site

1. Background and Statutory Authority

Section 10331 (a)(1) of the Affordable Care Act, requires that, by no later than January 1, 2011, we develop a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other eligible professionals who participate in the Physician Quality Reporting System (PQRS) under section 1848 of the Act.

CMS launched the first phase of Physician Compare on December 30, 2010 (*www.medicare.gov/physiciancompare*). In the initial phase, we posted the names of eligible professionals that satisfactorily submitted quality data for the 2009 PQRS, as required by section 1848(m)(5)(G) of the Act.

Section 10331(a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and for reporting periods that begin no earlier than January 1, 2012, we implement a plan for making publicly available through Physician Compare information on physician performance that provides comparable information on quality and patient experience measures. We met this requirement in advance of January 1, 2013, as outlined below, and intend to continue to address elements of the plan through rulemaking.

To the extent that scientifically sound measures are developed and are available, we are required to include, to the extent practicable, the following types of measures for public reporting:

- Measures collected under the PQRS.
- An assessment of patient health outcomes and functional status of patients.
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use.
- An assessment of efficiency.
- An assessment of patient experience and patient, caregiver, and family engagement.
- An assessment of the safety, effectiveness, and timeliness of care.
- Other information as determined appropriate by the Secretary.

As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan, we must include, to the extent practicable, the following:

- Processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary.
- Processes for physicians and eligible professionals whose information is being publicly reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare. This would consist of a 30-day preview period for all measurement performance data that will allow physicians and other eligible professionals to view their data as it will appear on the Web site in advance of publication. Details of the preview process will be communicated on the Physician Compare Initiative page on CMS.gov in advance of the preview period.
- Processes to ensure the data published on Physician Compare provides a robust and accurate portrayal of a physician's performance.
- Data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent applicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance.
- Processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of the patient.
- Processes to ensure timely statistical performance feedback is provided to physicians concerning the data published on Physician Compare.
- Implementation of computer and data infrastructure and systems used to support valid, reliable and accurate reporting activities.

Section 10331(d) of the Affordable Care Act requires us to consider input from multi-stakeholder groups in selecting quality measures for Physician Compare, which we note we are working to accomplish through a variety of means including rulemaking and various forms of stakeholder outreach. In developing the plan for making information on physician performance publicly available through Physician Compare, section 10331(e) of the Affordable Care Act requires the Secretary, as the Secretary deems appropriate, to consider the plan to transition to value-based purchasing for physicians and other practitioners that was developed under section 131(d) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted on July 15, 2008).

Under section 10331(f) of the Affordable Care Act, we are required to submit a report to the Congress, by January 1, 2015, on Physician Compare development, and include information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice. Initial work on this report is currently underway. Section 10331(g) of the Affordable Care Act provides that any time before that date, we may continue to expand the information made available on Physician Compare.

We believe section 10331 of the Affordable Care Act supports our overarching goals of providing consumers with quality of care information to make informed decisions about their healthcare, while encouraging clinicians to improve on the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, we intend to utilize Physician Compare to publicly report physician performance results.

2. Public Reporting of Physician Performance Data

Since the initial launch of the Web site, we have continued to build on and improve Physician Compare. In 2013, we launched a full redesign of Physician Compare offering significant improvements including a complete overhaul of the underlying database and a new Intelligent Search feature, addressing two of our stakeholders' primary critiques of the site and considerably improving functionality and usability. The primary source of administrative information on Physician Compare is the Provider Enrollment, Chain, and Ownership System (PECOS); as the sole source of verified Medicare professional information, PECOS remains the primary information source. However, with the redesign, we incorporated Medicare claims information to verify the information in PECOS to ensure only the most current and accurate information is included on the site.

With the redesign, users can now search for Medicare physicians and other healthcare professionals by defining a location—a ZIP code, a city/State combination, an exact address, or landmark—and by entering a medical specialty, health care professional or group practice name, a medical condition, body part, or organ system. The site produces a list of suggested specialties, as defined by the 855i Medicare Enrollment Form, users can choose related to their search term or a list of names, as appropriate.

Currently, users can view information about approved Medicare professionals such as name, primary and secondary specialties, practice locations, group affiliations, hospital affiliations that link to the hospital's profile on Hospital Compare as available, Medicare Assignment status, education, languages spoken, and American Board of Medical Specialties (ABMS) board certification information. In addition, for group practices, users can also view group practice names, specialties, practice locations, Medicare Assignment status, and affiliated professionals.

As required by 1848(m)(5)(G) of the Act, we are required to post on a CMS Web site the names of eligible professionals who satisfactorily report under the PQRS, as well as those eligible professionals who are successful electronic prescribers under the Medicare Electronic Prescribing (eRx) Incentive Program, and Physician Compare contains a link to the list of names. In addition to the list of names, there is a section on each individual's profile page listing the quality programs under which the specific individual satisfactorily reported or was a successful electronic prescriber. The program name is listed and a green check mark clearly indicates participation. These data will be updated annually with the most recent data available.

With the Physician Compare redesign, we have also added a quality programs section to each group practice profile page in order to indicate which group practices are satisfactorily reporting in Group Practice Reporting Option (GPRO) under the PQRS or the eRx Incentive program. We have also included a notation and check mark for individuals that participate in the Medicare EHR Incentive Program, as authorized by section 1848(o)(3)(D) of the Act. These data will be updated with the most recent data available.

As we indicated in the 2013 PFS final rule with comment period (77 FR 69166), we will include a check mark in the quality programs section of the profile page to note those individuals who report the PQRS Cardiovascular Prevention measures group in support of the Million Hearts Initiative. Finally, a check mark will be added to indicate those individuals who have earned a Maintenance of Certification Additional Incentive starting with data reported for CY 2013. We will update this information annually moving forward.

We are now instituting our plan for a phased approach to public reporting of performance information on Physician Compare. The first phase of our plan was finalized with the 2012 PFS final rule with comment period (77 FR 69166), where we established that PQRS GPRO measures collected through the GPRO Web interface during 2012 would be publicly reported on Physician Compare. These measures will be publicly reported on Physician Compare in CY 2014. We expanded our plan with the 2013 PFS final rule with comment period (77 FR 69166) where we established that the specific GPRO web interface measures that would be posted on Physician Compare include the Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) PQRS GPRO measures, and that we would develop and report composite measures for these measure groups in future years, if technically feasible. For data reported in 2013 under the GPRO, DM and CAD PQRS GPRO measures and composites collected via the GPRO web interface that meet the minimum sample size of 20 patients, and that prove to be statistically valid and reliable, will be publicly reported on Physician Compare in late CY 2014, if technically feasible. As we previously established, if the minimum threshold is not met for a particular measure, or the measure is otherwise deemed not to be suitable for public reporting, the group's performance rate on that measure will not be publicly reported.

In the Shared Savings Program final rule (76 FR 67948), we noted that because Accountable Care Organization (ACO) providers/suppliers that are eligible professionals are considered to be group practices for purposes of qualifying for a PQRS incentive under the Shared Savings Program, we would publicly report performance on quality measures as we report performance on quality measures for PQRS GPRO group practices. Public reporting of performance on these measures will be presented at the ACO level only.

In the CY 2013 PFS final rule with comment period (77 FR 69167), we also finalized our decision to publicly report Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) data for group practices of 100 or more eligible professionals reporting data in 2013 under the GPRO, and for ACOs participating in the Shared Savings Program. We anticipate posting these data on Physician Compare as early as 2014.

3. Future Development of Physician Compare

We will continue to phase in an expansion of Physician Compare over the next several years by incorporating quality measures from a variety of sources, as technically feasible. We previously finalized a decision to publicly report on Physician Compare the performance rates on a limited set of Web interface quality measures that group practices submit under the 2012 and 2013 PQRS GPRO Web interface (76 FR 73417 and 77 FR 69166).

For 2014, we propose to expand the quality measures posted on Physician Compare by publicly reporting performance on all measures collected through the GPRO Web interface for groups of all sizes participating in 2014 under the PQRS GPRO and for ACOs participating in the Medicare Shared Savings Program. These data would include measure performance rates for measures reported that met the minimum sample size of 20 patients, and that prove to be statistically valid and reliable. We will provide a 30-day preview period prior to publication of quality data on Physician Compare so that group practices and ACOs can view their data as it will appear on Physician Compare before it is publicly reported. CMS will detail the process for the 30-day preview and provide a detailed timeline and instructions for preview in advance of the start of the preview period.

For 2013 and 2014, we expanded the group reporting option for PQRS GPRO to include a registry reporting option, which we propose to further modify for data reported in 2014 under the PQRS GPRO registry option. Consistent with the requirement under section 10331(a)(2)(A) of the Affordable Care Act to make publicly available information on quality measures submitted by physicians and other eligible professionals under PQRS, we propose to publicly report on Physician Compare performance on certain measures that groups report via registries and EHRs in 2014 for the PQRS GPRO. Specifically, we propose to report, no earlier than 2015, performance on the GPRO registry and EHR measures identified below that can also be reported via the GPRO Web interface in 2014. By proposing to include on Physician Compare performance on these measures reported by participants under the GPRO through registries and EHRs, as well as the GPRO Web interface, we continue to provide beneficiaries with a consistent set of measures over time. For registry reporting, publicly reported measures would include:

- Diabetes: Hemoglobin A1c Poor Control.
- Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Medication Reconciliation.

• Preventive Care and Screening: Influenza Immunization.
• Pneumococcal Vaccination Status for Older Adults.
• Preventive Care and Screening: Breast Cancer Screening.
• Colorectal Cancer Screening.
• Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%).
• Adult Weight Screening and Follow-Up.
• Preventive Care and Screening: Screening for Clinical Depression.
• Coronary Artery Disease (CAD): Lipid Control.
• Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
• Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.
• Hypertension (HTN): Controlling High Blood Pressure.
• Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control.
• Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.

For EHR reporting, publicly reported measures would include:
• Diabetes: Hemoglobin A1c Poor Control.
• Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
• Preventive Care and Screening: Influenza Immunization.
• Pneumococcal Vaccination Status for Older Adults.
• Preventive Care and Screening: Breast Cancer Screening.
• Colorectal Cancer Screening.
• Adult Weight Screening and Follow-Up.
• Coronary Artery Disease (CAD): Lipid Control.
• Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
• Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.
• Hypertension (HTN): Controlling High Blood Pressure.
• Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control.
• Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.

Consistent with the requirement under section 10331(a)(2) of the Affordable Care Act to make comparable information on patient experience of care measures publicly available, we previously finalized a plan to post performance on patient experience survey-based measures from the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) (77 FR 44804) including the following patient experience of care measures for group practices participating in the PQRS GPRO (77 FR 44964):
• CAHPS: Getting Timely Care, Appointments, and Information.
• CAHPS: How Well Your Doctors Communicate.
• CAHPS: Patients' Rating of Doctor.
• CAHPS: Access to Specialists.
• CAHPS: Health Promotion and Education

These measures capture patients' experiences with clinicians and their staff, and patients' perception of care. We finalized a decision to publicly report performance on these measures on Physician Compare in 2014 for data collected for PY 2013 for group practices with 100 or more eligible professionals participating in the PQRS GPRO in 2013 and reporting data through the GPRO Web interface. At least for data reported for 2013, we noted that we would administer and collect patient experience survey data on a sample of the group practices' beneficiaries.

For ACOs participating in the Shared Savings Program, consistent with the PQRS policy of publicly reporting patient experience measures on Physician Compare starting with data collected for CY 2013, we will publicly report patient experience data in addition to the measure data reported through the GPRO Web interface (76 FR 67948). Specifically, the patient experience measures that would be reported for ACOs include the CG-CAHPS measures in the Patient/Caregiver Experience domain finalized in the Shared Savings Program final rule (76 FR 67889):
• CAHPS: Getting Timely Care, Appointments, and Information.
• CAHPS: How Well Your Doctors Communicate.
• CAHPS: Patients' Rating of Doctor.
• CAHPS: Access to Specialists.
• CAHPS: Health Promotion and Education.
• CAHPS: Shared Decision Making
• CAHPS: Health Status/Functional Status

For data reported for 2014, we propose to continue public reporting of these CG-CAHPS data for PQRS GPRO group practices of 100 or more eligible professionals participating in the GPRO via the Web interface and for Shared Savings Program ACOs reporting through the GPRO Web interface or other CMS-approved tool or interface. Consistent with what we finalized for CY 2013 under the PQRS GPRO, we will administer and fund the collection of data for these groups. As we will administer and collect the data for these surveys, we do not anticipate public reporting to impose any notable burden on these groups.

We believe these patient surveys are important tools for assessing beneficiary experience of care and outcomes, and under our authority under section 1848(m)(3)(C) of the Act to select the measures for which a group practice must report under the PQRS, we seek to encourage groups of 25 or more eligible professionals to report CG-CAHPS by proposing to make these measures available for reporting the PQRS and for the Value Based Payment Modifier. We propose to publicly report CY 2014 CG-CAHPS data for any group practice (regardless of size) that voluntarily chooses to report CG-CAHPS; however, CMS will not fund the surveys for these groups. CMS proposes to publically report comparable CG-CAHPS data collected by groups of any size collected via a certified CAHPS vendor.

We are dedicated to publicly reporting accurate, valid, and reliable data on Physician Compare and are aware that each group practice is unique in size and scope. We have closely evaluated the available data collection mechanisms, and are confident that CG-CAHPS is a well-tested collection mechanism with strong support from the healthcare community, and that it provides the best opportunity to collect useful and accurate data for the largest number of group practices. We propose to use only those survey domains that are applicable to group practices or ACOs respectively, and believe that these domains have been well tested, and will therefore provide the best data for the largest number of groups.

In the CY 2013 PFS final rule with comment period (77 FR 44804), we indicated our intention to publicly report performance rates on quality measures included in the 2014 PQRS and for individual eligible professionals consistent with the requirements under section 10331 of the Affordable Care Act to provide information about physicians and other eligible professionals who participate in PQRS. We believe that individual-level measure data is important in helping consumers make informed healthcare decisions and that this information should be posted on the site as soon as technically feasible. Therefore, we propose to publicly report comparable data, as noted below, collected for the CY 2014 PQRS via claims, EHR or registry from individual eligible professionals as early as CY

2015. Specifically, we propose to post individual measures reported by individual eligible professionals in line with those measures reported by groups through the GPRO Web interface. These measures include:

- Diabetes: Hemoglobin A1c Poor Control.
- Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Medication Reconciliation.
- Preventive Care and Screening: Influenza Immunization.
- Pneumococcal Vaccination Status for Older Adults.
- Preventive Care and Screening: Breast Cancer Screening.
- Colorectal Cancer Screening.
- Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%).
- Adult Weight Screening and Follow-Up.
- Preventive Care and Screening: Screening for Clinical Depression.
- Coronary Artery Disease (CAD): Lipid Control.
- Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
- Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.
- Hypertension (HTN): Controlling High Blood Pressure.
- Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control.
- Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.
- Falls: Screening for Fall Risk.
- Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control.
- Diabetes Mellitus: High Blood Pressure Control.
- Diabetes Mellitus: Hemoglobin A1c Control (<8%).

Additionally, and in support of the HHS-wide Million Hearts Initiative, we propose to publicly report, no earlier than 2015, performance rates on measures in the PQRS Cardiovascular Prevention measures group (77 FR 44803) at the individual eligible professional level for data collected in 2014 for the PQRS (Table 50).

We seek comment on posting performance on patient experience survey-based measures for individual eligible professionals starting with data collected for CY 2015.

In future years, we will consider expanding public reporting of, and seek comment on, measures that have been developed and collected by approved and vetted specialty societies for individual eligible professionals as well as data collected via the new qualified clinical data registry option being proposed under the PQRS. Additionally, we seek comment on publicly reporting participation by individual eligible healthcare professionals on initiatives such as Choosing Wisely, an initiative of the American Board of Internal Medicine Foundation.

We are committed to making Physician Compare a constructive tool for Medicare beneficiaries, successfully meeting the Affordable Care Act mandate, and providing consumers with information needed to make informed healthcare decisions. We have developed a plan, and begun implementing that plan with a phased approach of adding physician quality data to Physician Compare. We believe this staged approach to public reporting of physician quality information allows consumers access to information that is currently available while we continue to develop the infrastructure necessary to support additional types of data and information on physicians' quality measure performance. We intend to implement subsequent phases of the plan in future rulemaking, as needed.

We invite comments regarding our proposals to: (1) Publicly report performance rates on all quality measures that group practices submit through the GPRO web interface in 2014 under the PQRS GPRO and that ACOs participating in the Medicare Shared Savings Program submit using the GPRO web interface or another CMS-approved tool or interface; (2) publicly report performance on certain quality measures collected under the 2014 PQRS GPRO via registry and EHR reporting mechanisms; (3) publicly report performance on patient experience measures for 2014 both for group practices and ACOs and for group practices of 25 or more professionals who choose to voluntarily report CG-CAHPS data as part of their participation in the PQRS GPRO; (4) publicly report performance on certain measures that are reported by individual eligible professionals reporting through an EHR, registry, or claims during 2014 under the PQRS; and (5) in support of the HHS-wide Million Hearts Initiative, publicly report performance rates for measures included in the Cardiovascular Prevention measures group reported by individual eligible professionals participating in the 2014 PQRS.

We seek comment regarding: (1) Publicly report patient experience survey data under the PQRS for individual eligible professionals, starting with data reported in 2015; and (2) to publicly report participation by individual eligible healthcare professionals on initiatives such as Choosing Wisely, an initiative of the American Board of Internal Medicine Foundation.

For the above proposals, we note that we would only post data on Physician Compare as it is technically feasible and as the data are available.

H. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

There are several healthcare quality improvement programs that affect physician payments under the Medicare PFS. As we stated previously, we believe that alignment of these quality improvement programs—such as the EHR Incentive Program, Value-based Payment Modifier, and Medicare Shared Savings Program—is critical for programs involving physicians and other healthcare eligible professionals. The proposals that follow facilitate the alignment of programs, reporting systems, and quality measures. We believe that alignment of CMS quality improvement programs will decrease the burden of participation on physicians and allow them to spend more time and resources caring for beneficiaries. Furthermore, as the leaders of care teams and the healthcare systems, physicians and other clinicians serve beneficiaries both as frontline and system-wide change agents to improve quality. We believe that to improve quality, quality measurement and reporting is an important component. It is our intent that the following requirements will further improve alignment of physician-focused quality improvement programs, decrease burden and duplicative reporting for eligible professionals, increase engagement of physicians and other eligible professionals in quality improvement, and ultimately, lead to higher quality care for beneficiaries.

This section contains the requirements for the Physician Quality Reporting System (PQRS). The PQRS, as set forth in sections 1848(a), (k), and (m) of the Act, is a quality reporting program that provides incentive payments and payment adjustments to eligible professionals based on whether or not they satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. The regulation governing the PQRS is located at § 414.90. The program requirements for the 2007 through 2014 PQRS incentives and the 2015 PQRS payment adjustment that were

previously established, as well as information on the PQRS, including related laws and established requirements, are available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*. In addition, the 2011 PQRS and eRx Experience Report, which provides information about eligible professional participation in PQRS, is available for download at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*.

In the CY 2013 PFS final rule with comment period (77 FR 69170), we finalized certain requirements for the 2013 and 2014 PQRS incentives, as well as 2015 and 2016 PQRS payment adjustments. We also finalized certain requirements for future years, such as the reporting periods for the PQRS payment adjustment, as well as requirements for the various PQRS reporting mechanisms. Below, we propose to change some requirements for the 2014 PQRS incentive and 2016 PQRS payment adjustment, as well as to make changes to the PQRS measure set. Furthermore, we introduce our proposals for a new PQRS reporting option—satisfactory participation in a qualified clinical data registry. We then seek comment on a general plan for future years for PQRS, so that we may continue to consider stakeholder feedback as we develop policies and proposals for the future.

1. Proposed Changes to § 414.90

As noted previously, the regulation governing the PQRS is located at § 414.90. We are proposing the following changes and technical corrections to § 414.90:

- Under § 414.90(b), we are proposing to modify the definition of administrative claims to eliminate the words ''the proposed'' in the phrase ''on the proposed PQRS quality measures.'' We are proposing to make this technical change because this language was inadvertently included in the final regulation despite the fact that the quality measures that eligible professionals report under the PQRS were finalized in the CY 2013 PFS final rule with comment period (77 FR 69364).
- We propose to modify § 414.90(f) to include the term ''for satisfactory reporting'' after the title ''Use of consensus-based quality measures for satisfactory reporting.'' We are adding the term ''for satisfactory reporting'' so that it is clear that the paragraph refers to satisfactory reporting, not the new standard of satisfactorily participating in a qualified clinical data registry.
- We propose to modify the paragraph heading of § 414.90(g) to add the term ''satisfactory reporting'', so that the title of the paragraph reads ''Satisfactory reporting requirements for the incentive payments.'' We are proposing to make this change so that it is clear that the paragraph refers to satisfactory reporting, not the new standard of satisfactorily participating in a qualified clinical data registry.
- We propose to modify the paragraph heading of § 414.90(h) to add the term ''satisfactory reporting'', so that the title of the paragraph reads ''Satisfactory reporting requirements for the incentive payments.'' We are proposing to make this change so that it is clear that the paragraph refers to satisfactory reporting, not the new standard of satisfactorily participating in a qualified clinical data registry.
- We propose to delete paragraph § 414.90(i)(4), because § 414.90(i)(4) list requirements that are identical to § 414.90(i)(3). Therefore, § 414.90(i)(4) is redundant.

In addition, we are considering further revising the regulation at § 414.90 to list all the specific satisfactory reporting requirements for the 2014 PQRS incentive and 2016 PQRS payment adjustment, so that the different reporting requirements are specified in the regulation. We seek public comment on these proposals.

2. Participation as a Group Practice in the Group Practice Reporting Option (GPRO)

a. Proposed Changes to the Self-nomination, or Registration, Requirement for Group Practices To Be Selected to Participate in the GPRO

In the CY 2013 PFS final rule with comment period (77 FR 69172), we finalized requirements for the self-nomination process group practices must follow to participate in the PQRS GPRO. We propose to make two changes to the previously established self-nomination process for group practices. First, we propose to change the deadline for group practices to submit a self-nomination statement, or register, to participate in the PQRS GPRO. We previously established, that in order for a group practice to participate in PQRS under the GPRO, the group practice must submit a self-nomination statement, or register, via the web by October 15 of the year in which the reporting period occurs. Starting with reporting periods occurring in 2014, we propose to change this deadline to September 30 of the year in which the reporting period occurs (that is September 30, 2014 for reporting periods occurring in 2014). We believe that the proposed deadline still gives group practices a reasonable amount of time to make a decision on whether to participate in the PQRS GPRO while allowing CMS more time to pull samples to populate the GPRO web-interface for those group practices that select that particular reporting mechanism. Second, we propose that group practices comprised of 25 or more individual eligible professionals that wish to report the CG CAHPS survey measures (which are discussed later in this section) would be required to elect to report the CG CAHPS survey measures via the web as well. The Web site that a group practice would use to elect to report the CG CAHPS survey measures would be the same Web site used by group practices to register to participate in the PQRS GPRO and used by group practices comprised of 10–99 eligible professionals to elect quality tiering for the Value-based Payment Modifier set forth in section III.M of this proposed rule. We believe that providing a single Web site whereby group practices may make multiple elections (such as submitting the self-nomination statement to register to participate in the PQRS GPRO, be evaluated for the PQRS GPRO using CG CAHPS measures, and also elect quality tiering for the Value-based Payment Modifier) would be desirable for group practices. We seek public comment on the proposed changes to the PQRS GPRO self-nomination process.

3. Proposed Requirements for the PQRS Reporting Mechanisms

The PQRS includes the following reporting mechanisms: Claims, registry, EHR (including direct EHR products and EHR data submission vendor products), administrative claims, and the GPRO web-interface. Section 414.90(g) and (h) govern which reporting mechanisms are available for use by individuals and group practices for the PQRS incentive and payment adjustment. This section contains our proposed changes to these PQRS reporting mechanisms. In addition, this section contains our proposals for two new PQRS reporting mechanisms. We propose a new certified survey vendor reporting mechanism for purposes of reporting CG CAHPS measures described below and a qualified clinical data registry reporting mechanism under the new PQRS ''satisfactory participation'' option.

a. Registry-Based Reporting Mechanism

In the CY 2013 PFS final rule with comment period, we finalized the following requirement for registries to become qualified to participate in PQRS for 2013 and beyond: Be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 3 measures (77 FR 69180). Since, as we describe in more detail below, we are proposing to increase the number of measures eligible professionals would be required to report for the 2014 PQRS incentive from 3 to 9 measures covering at least 3 of the National Quality Strategy domains, we are proposing to change this registry requirement as follows: A qualified registry must be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 9 measures covering at least 3 of the National Quality Strategy domains. We seek public comment on this proposal.

b. Certified Survey Vendors

As discussed later in this section, we are proposing to allow group practices comprised of 25 or more eligible professionals to report CG CAHPS survey measures. The data collected on these CAHPS survey measures would not be transmitted to CMS via the previously established PQRS group practice reporting mechanisms (registry, EHR, or GPRO web interface). Rather, the data must be transmitted through a survey vendor. Therefore, to allow for the survey vendor to transmit survey measures data to CMS, we are proposing to modify § 414.90(b), § 414.90(g)(3), and § 414.90(h)(3) to propose a new reporting mechanism—the certified survey vendor.

In addition, § 414.90(g)(3), and § 414.90(h)(3) currently requires group practices to use only one mechanism to meet the requirements for satisfactory reporting (that is, CMS will not combine data submitted under multiple reporting mechanism to determine if the requirements for satisfactory reporting are met). As discussed further below, we propose that a group practice choosing to report CG CAHPS survey measures would be required to select an additional reporting mechanism to meet the requirements for satisfactory reporting for both the 2014 PQRS incentive and the 2016 PQRS payment adjustment. Therefore, we propose to modify § 414.90(g)(3), and § 414.90(h)(3) to indicate that groups selecting to use the certified survey vendor would be the exception to this requirement.

Specifically, for purposes of PQRS, we are proposing to modify § 414.90(b) to define a certified survey vendor as a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS.

To obtain CMS certification, we propose that vendors would be required to undergo training, meet CMS standards on how to administer the survey, and submit a quality assurance plan. CMS would provide the identified vendor with an appropriate sample frame of beneficiaries from the group. The vendor would also be required to administer the survey according to established protocols to ensure valid and reliable results. Survey vendors would be supplied with mail and telephone versions of the survey in electronic form, and text for beneficiary pre-notification and cover letters. Surveys can be administered in English, Spanish, Cantonese, Mandarin, Korean, Russian and/or Vietnamese. Vendors would be required to use appropriate quality control, encryption, security and backup procedures to maintain survey response data. The data would then be securely sent back to CMS for scoring and/or validation. To ensure that a vendor possesses the ability to transmit survey measures data for a particular program year, we propose to require survey vendors to undergo this certification process for each year in which the vendor seeks to transmit survey measures data to CMS. We seek public comment on these proposals.

4. Proposed Changes to the Criteria for the Satisfactory Reporting for Individual Eligible Professionals for the 2014 PQRS Incentive—Individual Quality Measures Submitted via Claims and Registries and Measures Groups Submitted via Claims

Individual eligible professionals may currently report PQRS quality measures data to meet the criteria for satisfactory reporting for the 2014 PQRS incentive via the claims, registry, and EHR-based reporting mechanisms. This section contains our proposed changes to the criteria for satisfactory reporting of individual quality measures via claims and registries by individual eligible professionals for the 2014 PQRS incentive. Please note that we are not proposing to modify the criteria for satisfactory reporting of individual quality measures via EHR that were established in the CY 2013 PFS final rule with comment period (see Table 91, 77 FR 69194).

a. Proposed Changes to the Criterion for Satisfactory Reporting of Individual Quality Measures via Claims for Individual Eligible Professionals for the 2014 PQRS Incentive

For 2014, in accordance with § 414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. In the CY 2013 PFS final rule with comment period (*see* Table 91, 77 FR 69194), to maintain the reporting criterion with which individual eligible professionals are familiar, we finalized the same satisfactory reporting criterion for the submission of individual quality measures via claims that we finalized in previous years: For the 12-month reporting period for the 2014 PQRS incentive, report at least 3 measures, OR, if less than 3 measures apply to the eligible professional, report 1–2 measures, and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an eligible professional who reports fewer than 3 measures via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation (MAV) process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures (77 FR 69188).

For the reasons described below and based on our authority to revise the criteria for satisfactory reporting for the 2014 PQRS incentive under section 1848(m)(3)(d) of the Act, we propose to change the criterion for the satisfactory reporting of individual, claims-based measures by individual eligible professionals for the 2014 PQRS incentive as follows: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures, covering at least 3 of the National Quality Strategy domains, OR, if less than 9 measures apply to the eligible professional, report 1–8 measures, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an eligible professional who reports fewer than 9 measures via the claims-based reporting mechanism, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported

quality data codes for additional measures.

We note that this proposal would increase the number of measures an eligible professional is required to report via the claims-based reporting mechanism from 3 measures to 9. We understand that this is a significant increase in the number of measures an eligible professionals is required to report. However, we believe that the need to collect enough quality measures data to better capture the picture of the care being furnished to a beneficiary, especially when this data may be used to evaluate an eligible professional's quality performance under the Value-based Payment Modifier, justifies the increase in measures.

We seek public comment on the proposed change to the criterion for the satisfactory reporting of individual quality measures via claims for individual eligible professionals for the 2014 PQRS incentive.

b. Proposed Changes to the Criterion for Satisfactory Reporting of Individual Quality Measures via Registry for Individual Eligible Professionals for the 2014 PQRS Incentive

In the CY 2013 PFS final rule with comment period, to maintain reporting criterion with which individual eligible professionals are familiar, we finalized the same satisfactory reporting criterion for individual eligible professionals to report individual quality measures via registry that we finalized in previous years: For the 12-month reporting period for the 2014 PQRS incentive, report at least 3 measures and report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (77 FR 69189). We propose to change this reporting criterion for individual eligible professionals reporting via registry for the 2014 PQRS incentive to the following: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

We note that this proposal would increase the number of measures an eligible professional is required to report via the registry-based reporting mechanism from 3 measures to 9 covering at least 3 of the National Quality Strategy domains. We understand that this is a significant increase in the number of measures an eligible professional is required to report. However, similar to the reasons we provided for proposing to increase the measure threshold from 3 measures to 9 for the claims-based reporting mechanism, we believe that the need to collect enough quality measures data to better capture the picture of the care being furnished to a beneficiary, especially when this data may be used to evaluate an eligible professional's quality performance under the Value-based Payment Modifier, justifies the change. We believe that collecting data on 9 measures applicable to an eligible professional's practice as opposed to 3 measures would provide us with a better picture of the overall quality of care furnished by that eligible professional for purposes of having PQRS reporting being used to assess quality performance under the Value-based Payment Modifier. We also note that, as PQRS has used this same 3-measure criterion since the registry-based reporting mechanism was introduced in 2010, it would be conceivable that we would eventually propose to increase the number of measures an eligible professional is required to report. Our proposal to increase the number of measures reported via claims and registry would align with our established reporting option for the EHR-based reporting mechanism or the 2014 PQRS incentive, which requires the reporting of 9 measures covering 3 of the National Quality Strategy domains (77 FR 69189).

In addition, we note that this proposal would also decrease the number of patients for which an eligible professional must report for each measure from 80 percent to 50 percent of an eligible professional's applicable patients. We are proposing to drop the percentage threshold from 80 to 50 percent primarily to align our percentage thresholds for registry reporting with the percentage threshold established for reporting via the claims-based reporting mechanism. We believe it is appropriate to drop the percentage threshold to 50, particularly since we are proposing to also increase the number of measures an eligible professional is required to report via the registry-based reporting mechanism from 3 to 9 measures covering at least 3 of the National Quality Strategy domains. The criteria for satisfactory reporting that we are proposing for the 2014 PQRS incentive payment are described in Table 24.

We seek public comment on the proposed changes to the criterion for the satisfactory reporting of individual quality measures via registry for individual eligible professionals for the 2014 PQRS incentive.

c. Proposed Changes to the Criterion for Satisfactory Reporting of Measures Groups via Claims for Individual Eligible Professionals for the 2014 PQRS Incentive

In the CY 2013 PFS final rule with comment period, we finalized the following criteria for satisfactory reporting for individual eligible professionals to report measures groups via claims: Report at least 1 measures group and report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a zero percent performance rate will not be counted (77 FR 69192). Since finalizing this criterion, we have recently published and analyzed the 2011 PQRS and eRx Experience Report, which provides a summary of PQRS reporting trends from 2007 through 2011, to determine where we may work to further streamline the reporting options available under the PQRS. The PQRS and eRx Experience Report stated that the number of eligible professionals who participated via claims-based measures groups reporting mechanism grew more than three-fold between 2008 and 2011. However, according to Appendix 8 of the PQRS and eRx Experience Report titled ''Eligible Professionals who Participated by Reporting Measures Groups through the Claims Reporting Mechanism for the Physician Quality Reporting System, by Specialty (2008 to 2011),'' only 4,472 eligible professionals used this reporting option. Meanwhile, the Experience Report further shows that the option to report measures groups via registry has grown at an even faster rate with 12,894 participants in 2011. Therefore, in an effort to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used, we are proposing to remove this satisfactory reporting criterion for the 2014 PQRS incentive. Please note that, since we are proposing to remove this reporting criterion, the only manner in which an eligible professional would be able to report a PQRS measures group would be via registry. We seek public comment on this proposal.

5. Proposed Criteria for Satisfactory Reporting for the 2016 PQRS Payment Adjustment for Individual Eligible Professionals Using the Claims and Registry Reporting Mechanisms

Section 1848(a)(8) of the Act, as added by section 3002(b) of the

Affordable Care Act, provides that for covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

In the CY 2013 PFS final rule, we finalized seven different criteria for the satisfactory reporting by individual eligible professionals of data in PQRS quality measures for the 2016 PQRS payment adjustment (*see* 77 FR 69200–69204 and Table 91 at 77 FR 69194). Although we are retaining five of the final criteria for satisfactory reporting by individual eligible professionals of data on PQRS quality measures for the 2016 PQRS payment adjustment, we propose to eliminate two criteria, revise another, and include two additional criteria (based on two of the existing criteria). Specifically, we propose to remove the following criterion we previously finalized for the CY 2016 payment adjustment for individual eligible professionals reporting measures groups through claims (77 FR 69200 and Table 91, 77 FR 69164): Report at least 1 measures group and report each measures group for at least 20 Medicare Part B FFS patients (Measures groups containing a measure with a zero percent performance rate will not be counted). Our proposal to remove this criterion would correspond to the same proposal we are making, as discussed above, for the 2014 PQRS incentive for individual eligible professionals. As we indicated, we believe it is important to streamline the program and eliminate criteria for reporting options that are not widely used.

We also propose to remove the following criterion we previously finalized for the 2016 payment adjustment for individual eligible professionals reporting individual measures through a qualified registry (77 FR 69200 and Table 91, 77 FR 69164): Report at least 3 measures, and report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measures applies (Measures with a zero percent performance rate will not be counted). Finally, to maintain some consistency and to otherwise align with the criteria we are proposing for the 2014 PQRS incentive for individual eligible professionals, we are proposing two other criteria for satisfactory reporting by individual eligible professionals for the 2016 PQRS payment adjustment using the claims and registry reporting mechanisms. Specifically, we propose the following criterion for reporting individual measures via claims by individual eligible professionals for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures, covering at least 3 of the National Quality Strategy domains, OR, if less than 9 measures apply to the eligible professional, report 1–8 measures, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. Similarly, for the same reasons we discussed previously, we propose the following criterion for reporting individual measures via qualified registry by individual eligible professionals for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

Please note that in the CY 2013 PFS final rule, we finalized the same criteria for satisfactorily reporting data on quality measures for covered professional services for the 2016 PQRS payment adjustment as those for the 2014 PQRS incentive for individual eligible professionals (77 FR 69200). However, if the proposals we are making in this proposed rule were finalized, there would be some differences between the criteria for satisfactory reporting for the 2016 PQRS payment adjustment and the 2014 PQRS incentive. In particular, there would be one more criterion for satisfactory reporting for the 2016 payment adjustment than for the 2014 PQRS incentive with respect to claims-based reporting, but the other criteria would otherwise align. Although we considered, as an alternative, to propose to remove the criterion we previously finalized for the 2016 payment adjustment for individual eligible professionals reporting individual measures through claims, we believe it is still important to offer as many options as possible for the 2016 PQRS payment adjustment, particularly since the penalty phase is relatively new under the PQRS. We also note that it would remain true that if an individual eligible professional were to meet any of the criteria for satisfactory reporting for the 2014 PQRS incentive, the individual eligible professional would meet the requirements for satisfactory reporting for the 2016 PQRS payment adjustment (note, however, that the reverse would not necessarily be true since there would be one additional criterion for satisfactory reporting for the 2016 PQRS payment adjustment that would not apply to the 2014 PQRS incentive).

The criteria for satisfactory reporting that we are proposing for the 2016 PQRS payment adjustment are described in Table 25. We believe such alignment still serves to reduce reporting burden, and as we have noted previously, we believe that proposing similar criteria for satisfactory reporting by individual eligible professionals for the 2014 PQRS incentive and 2016 PQRS payment adjustment is appropriate because the reporting period for the 2014 PQRS incentive and 2016 PQRS payment adjustment coincide. As we continue to implement the PQRS payment adjustment and fully implement the value-based payment modifier in 2017, it is our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive.

We seek public comment on our proposed satisfactory reporting criteria for individual eligible professionals for the 2016 PQRS payment adjustment, including the alternative proposal considered for individual eligible professionals reporting individual measures through the claims-based reporting mechanism.

6. Proposals Related to Satisfactory Participation in a Qualified Clinical Data Registry by Individual Eligible Professionals

Section 601(b) of the American Taxpayer Relief Act of 2012 amends section 1848(m)(3) of the Act, by redesignating subparagraph (D) as subparagraph (F) and adding new subparagraph (D), to provide for a new standard for individual eligible professionals to satisfy the PQRS beginning in 2014, based on satisfactory participation in a qualified clinical data registry. Below, we set forth our proposals for implementing this provision, including the proposed requirements for qualified clinical data registries and our proposals for individual eligible professionals to

satisfactorily participate in a qualified clinical data registry with respect to the 2014 PQRS incentive and 2016 PQRS payment adjustment.

On February 7, 2013, CMS published a Request for Information titled ''Medicare Program; Request for Information on the Use of Clinical Quality Measures (CQMs) Reported Under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs'' (78 FR 9057). The Request for Information included a solicitation for comments about section 601(b) of the American Taxpayer Relief Act of 2012. CMS received over 100 comments on this Request for Information, and much of the information provided in these comments were used to shape the proposals set forth in this section.

a. Proposed Definition of a Qualified Clinical Data Registry

Under section 1848(m)(3)(D) of the Act, as amended and added by section 601(b)(1) of the American Taxpayer Relief Act of 2012 (Pub. L. 112–240, enacted January 2, 2013), for 2014 and subsequent years, the Secretary shall treat an eligible professional as satisfactorily submitting data on quality measures if, in lieu of reporting measures under subsection (k)(2)(C), the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry for the year. Section 1848(m)(3)(E) of the Act, as added by section 601(b)(1) of the American Taxpayer Relief Act of 2012, authorizes the Secretary to define a qualified clinical data registry under the PQRS. Specifically, the Secretary is required to establish requirements for an entity to be considered a qualified clinical data registry (including that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to carry out the provision). And in establishing such requirements, the Secretary must take certain factors into consideration.

Generally, registries are entities that collect data related to patients with a specific diagnosis, condition, or procedure. In fact, the collection and submission of PQRS quality measures data on behalf of eligible professionals are the functions a traditional ''qualified registry'' currently performs under the PQRS for purposes of eligible professionals satisfactorily reporting. The majority of commenters in response to the February 7, 2013 Request for Information stated that these qualified clinical data registries should serve additional roles aimed at quality improvement other than collecting and transmitting quality data to CMS. The commenters saw qualified clinical data registries as entities that should be at the forefront of quality improvement. We agree with the commenters. Therefore, we believe that a ''qualified clinical data registry'' specified under section 1848(m)(3)(E) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, should serve additional roles that foster quality improvement in addition to the collection and submission of quality measures data.

Section 1848(m)(3)(E)(ii) of the Act, as added by section 601(b)(1) of the American Taxpayer Relief Act of 2012, provides that, when determining whether an entity should be considered a qualified clinical data registry, the Secretary shall take into consideration whether the entity:

- Has in place mechanisms for the transparency of data elements and specifications, risk models, and measures;
- Requires the submission of data from participants with respect to multiple payers;
- Provides timely performance reports to participants at the individual participant level; and
- Supports quality improvement initiatives for participants.

As an example of quality improvement initiatives by a clinical data registry, we note that the Society of Thoracic Surgeons established the STS National Database in 1989 for the purpose of quality assessment, improvement, and patient safety among cardiothoracic surgeons. The STS National Database, which serves a traditional qualified registry under the PQRS, provides:

- A standardized, nationally benchmarked tool for assessing the care of patients undergoing cardiothoracic operations;
- The opportunity to participate in national quality improvement efforts for cardiothoracic surgery that have an impact at the local, regional, and national levels;
- A mechanism to target specific areas for clinical practice improvement;
- The ability to investigate regional and national practice patterns in cardiothoracic surgery; and
- The ability to conduct clinical and comparative effectiveness research using national aggregate data set.

While we do not believe that it is necessary for a qualified clinical data registry to possess all of these characteristics for purposes of the PQRS, we do believe that it is important for a qualified clinical data registry to possess the following characteristics:

- Benchmarking capacity for assessing the care furnished to patients by the eligible professionals participating in the qualified clinical data registry. We believe it is important that a qualified clinical data registry possess benchmarking capacity in order to be able to compare the quality of care furnished by eligible professionals so that eligible professionals using the qualified clinical data registry are aware of how the care they furnished is rated as compared to other professionals. Eligible professionals would be able to use this information to adjust the care they provide, if appropriate. While having the capacity to benchmark performance nationally is preferable, we believe that a qualified clinical data registry should, at a minimum, possess the capacity to benchmark performance across the eligible professionals using the qualified clinical data registry.
- The ability to provide timely and frequent feedback to its eligible professionals. We believe it is important for eligible professionals using a clinical data registry to receive frequent and timely feedback on the quality measures data they report through the qualified clinical data registry. A traditional PQRS registry is required to provide at least 2 feedback reports to eligible professionals using the registry. Since we believe that qualified clinical data registries should possess a more robust system, we believe that qualified clinical data registries should provide timely feedback at least quarterly so eligible professionals could view their reporting at least 4 times during the yearly reporting period.

Therefore, based on CMS' authority to define a qualified clinical data registry under section 1848(m)(3)(E) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, and accounting for the considerations addressed in section 1848(m)(3)(E)(ii) of the Act and for the reasons stated above, we propose to modify § 414.90(b) to add a proposed definition for a qualified clinical data registry. Specifically, we propose to define a ''qualified clinical data registry'' for purposes of the PQRS as a CMS-approved entity (such as a registry, certification board, collaborative, etc.) that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care furnished to patients.

First, we propose that a qualified clinical data registry must be able to submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible

professionals have satisfactorily participated in PQRS. We propose that a qualified clinical data registry must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures. Second, with regard to the consideration under section 1848(m)(3)(E)(ii)(II) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012 that requires the submission of data from participants with respect to multiple payers, we propose that the data a qualified clinical data registry submitted to CMS for purposes of demonstrating satisfactory participation be quality measures data on multiple payers, not just Medicare patients.

Third, with regard to the consideration under section 1848(m)(3)(E)(ii)(III) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, that a qualified clinical data registry provide timely performance reports to participants at the individual participant level, we propose that a qualified clinical data registry must provide timely feedback at least quarterly on the measures for which the qualified clinical data registry would report on the individual eligible professional's behalf for purposes of the eligible professional meeting the criteria for satisfactory participation under PQRS.

Fourth, to address section 1848(m)(3)(E)(ii)(IV) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, regarding whether a qualified clinical data registry supports quality improvement initiatives for its participants, we propose to require that a qualified clinical data registry possess a method to benchmark the quality of care measures an eligible professional provides with that of other eligible professionals performing the same or similar functions. Benchmarking would require that a qualified clinical data registry provide metrics to compare the quality of care its participating eligible professional provides. For example, the National Committee for Quality Assurance (NCQA) provides national and regional benchmarks for certain measures. Adopting benchmarks such as those provided by NCQA could serve to satisfy this requirement.

Please note that it is possible for an entity to serve as a traditional, qualified registry and/or a qualified clinical data registry under the PQRS.

b. Proposed Requirements for a Qualified Clinical Data Registry

As we noted above, we are required, under section 1848(m)(3)(E)(i) of the Act, to establish requirements for an entity to be considered a qualified clinical data registry. Such requirements shall include a requirement that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to carry out this subsection. Section 1848(m)(3)(E)(iv) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, requires CMS to consult with interested parties in carrying out this provision.

Pursuant to this authority to establish the requirements for an entity to be considered a qualified clinical data registry, we are proposing the following requirements that an entity must meet to serve as a qualified clinical data registry under the PQRS:

First, we are proposing the following requirements to ensure that the entity seeking to become a qualified clinical data registry is well-established:

- Be in existence as of January 1 the year prior to the year for which the entity seeks to become a qualified clinical data registry (for example, January 1, 2013, to be eligible to participate for purposes of data collected in 2014). This proposed requirement is also required of a traditional qualified registry. We believe it is important for an entity to test out its business practices to ensure that the practices it adopts truly foster the improvement of quality care prior to seeking to become a qualified clinical data registry. We believe that entities that have been in existence for less than one year prior to the year for which the entity seeks to become a qualified clinical data registry have not had an adequate opportunity to do so.
- Have at least 100 clinical data registry participants by January 1 the year prior to the year for which the entity seeks to submit clinical quality measures data (for example, January 1, 2013, to be eligible to participate under the program with regard to data collected in 2014). Please note that not all participants would be required to participate in PQRS. We are proposing this requirement to ensure that the entity seeking to become a qualified clinical data registry is sufficient in size and technical capability. As we believe that a qualified clinical data registry should be more robust in technical capabilities than a traditional PQRS-qualified registry, we believe that a qualified clinical data registry should be sufficiently larger in size than a traditional PQRS-qualified registry. Therefore, whereas we only required a traditional PQRS-qualified registry to have at least 25 registry participants, we believe it is appropriate that we require that a qualified clinical data registry have at least 100 participants.
- Not be owned or managed by an individual, locally-owned, single-specialty group (for example, single-specialty practices with only 1 practice location or solo practitioner practices would be precluded from becoming a qualified clinical data registry).

In addition, for transparency purposes, we propose that a qualified clinical data registry must:

- Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the qualified clinical data registry's receipt of patient-specific data from the eligible professionals as well as the qualified clinical data registry's public disclosure of quality measure results.
- Describe to CMS the cost for eligible professionals that the qualified clinical data registry charges to submit data to CMS.

We are also proposing to require qualified clinical data registries to meet the following requirements pertaining to the transmission of quality measures data to CMS:

- To ensure that the qualified clinical data registry is compliant with applicable privacy and security laws and regulations, the entity must describe its plan to maintain Data Privacy and Security for data transmission, storage and reporting.
- Comply with a CMS-specified secure method for quality data submission.
- Provide information on each measure to be reported by an eligible professional, including a summary of supporting evidence/rationale, title, numerator, denominator, exclusions/exceptions, data elements and value sets in addition to measure level reporting rates, patient-level demographic data and/or the data elements needed to calculate the reporting rates by TIN/NPI.
- Submit an acceptable ''validation strategy'' to CMS by March 31 of the reporting year the entity seeks qualification (for example, if an entity wishes to become qualified for participation with regard to data collected in 2014, this validation strategy would be required to be submitted to CMS by March 31, 2014). A validation strategy would detail how the qualified clinical data registry will determine whether eligible professionals succeed in reporting clinical quality measures. Acceptable

validation strategies often include such provisions as the entity being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method. For a template for data validation and integrity, please also see the requirements for certification of an EHR product by the Office of the National Coordinator for Health Information Technology (ONC) that are explained at *http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method*.

- Perform the validation outlined in the strategy and send evidence of successful results to CMS by June 30 of the year following the reporting period (for example, June 30, 2015, for data collected in the reporting periods occurring in 2014).
- Obtain and keep on file for at least 7 years signed documentation that each holder of an NPI whose data are submitted to the qualified clinical data registry has authorized the registry to submit quality measure results and numerator and denominator data and/or patient-specific data on beneficiaries to CMS for the purpose of PQRS participation. This documentation would be required to be obtained at the time the eligible professional signs up with the qualified clinical data registry to submit quality measures data to the qualified clinical data registry and would be required to meet any applicable laws, regulations, and contractual business associate agreements.
- Upon request and for oversight purposes, provide CMS access to the qualified clinical data registry's database to review the beneficiary data on which the qualified clinical data registry-based submissions are based or provide to CMS a copy of the actual data.
- Prior to CMS posting the list of qualified clinical data registries for a particular year, verify the information contained on the list (includes names, contact information, measures, cost, etc.) and agree to furnish/support all of the services listed on the list.
- Make available to CMS samples of patient level data to audit the entity for purposes of validating the data submitted to CMS by the qualified clinical data registry, if determined to be necessary.
- The entity must provide information on how the entity collects quality measurement data, if requested.
- By March 31 of the year in which the entity seeks to participate in PQRS as a qualified clinical data registry, the entity must publically post (on the entity's Web site or other publication available to the public) a detailed description (rationale, numerator, denominator, exclusions/exceptions, data elements) of the quality measures it collects to ensure transparency of information to the public.
- The entity must report, on behalf of its individual eligible professional participants, a minimum of 9 measures that cross 3 National Quality Strategy domains.
- The entity, on behalf of its individual eligible professional participants, must report on at least one outcomes-based measure (defined in this section below).
- The entity, on behalf of its individual eligible professional participants, must report on a set of measures from one or more of the following categories: CG-CAHPS; NQF endorsed measures (information of which is available at *http://www.qualityforum.org/Home.aspx*); current PQRS measures; measures used by boards or specialty societies; and measures used in regional quality collaboratives.
- The entity must demonstrate that it has a plan to publicly report their quality data through a mechanism where the public and registry participants can view data about individual eligible professionals, as well as view regional and national benchmarks. As an alternative, we considered requiring that the entity must benchmark within its own registry for purposes of determining relative quality performance where appropriate.
- The entity must demonstrate that it has a plan to risk adjust the quality measures data for which it collects and intends to transmit to CMS, where appropriate. Risk adjustment has been described as a corrective tool used to level the playing field regarding the reporting of patient outcomes, adjusting for the differences in risk among specific patients (*http://www.sts.org/patient-information/what-risk-adjustment*). Risk adjustment also makes it possible to compare performance fairly. For example, if an 86 year old female with diabetes undergoes bypass surgery, there is less chance for a good outcome when compared with a healthy 40 year old male undergoing the same procedure. To take factors into account which influence outcomes, for example, advanced age, emergency operation, previous heart surgery, a risk adjusted model is used to report surgery results.

Should CMS find, pursuant to an audit, that a qualified clinical data registry has submitted inaccurate data, CMS proposes to disqualify the qualified clinical data registry, meaning the entity will not be allowed to submit quality measures data on behalf of its eligible professionals for purposes of meeting the criteria for satisfactory participation for the following year. Should an entity be disqualified, the entity must again become a qualified clinical data registry before it may submit quality measures data on behalf of its eligible professionals for purposes of the individual eligible professional participants meeting the criteria for satisfactory participation under the PQRS. Additionally, we propose that the inaccurate data collected would be discounted for purposes of an individual eligible professional meeting the criteria for satisfactory participation in a qualified clinical data registry. We seek comments on these proposals.

As we noted, section 1848(m)(3)(E)(i) of the Act, as added by section 601(b) of the American Tax Relief Act of 2012, requires us to establish requirements for an entity to be considered a qualified clinical data registry, including that the entity provide us with such information, at such times, and in such manner, as we determine necessary to carry out the provision. Given the broad discretion afforded under the statute, we propose that qualified clinical data registries provide CMS with the quality measures data it collects from its eligible professional participants. We believe it is important that a qualified clinical data registry provide such data for a number of reasons. As we discuss in greater detail below, we believe such information is necessary for purposes of determining whether individual eligible professionals have satisfactorily participated in a clinical qualified data registry under the PQRS. In addition, as discussed in section K, we are proposing to use the quality measures data reported under the PQRS to assess eligible professionals with regard to applying the Value-based Payment Modifier in an upward, downward, and neutral adjustment to an eligible professional's Medicare Part B PFS charges. Therefore, we propose to require that qualified clinical data registries submit quality measures data to CMS. Specifically, to further ensure that the quality measures data elements are reported to CMS in standardized manner, we propose to require that qualified clinical data registries be able to collect all needed data elements and transmit the data on quality measures to CMS, upon request, in one of two formats, either via a CMS-approved XML format or via the Quality Reporting

Document Architecture (QRDA) category III format. The CMS-approved XML format is consistent with how traditional qualified registries under the PQRS transmit data on quality measures to CMS. While our preference would be to receive data on quality measures via the QRDA category III format only since the QRDA category III format is one of the formats we require for an EP's EHR or an EHR data submission vendor to submit quality measures data (see 77 FR 69183), we understand that the quality measures data collected by qualified clinical data registries vary and that these qualified clinical data registries may not be equipped to submit quality measures data to CMS using the QRDA category III format. In future years, it is our intention to require all qualified clinical data registries to provide quality measures data via the QRDA category III format.

To ensure that the data provided by the qualified clinical data registry is correct, we propose to require that qualified clinical data registries provide CMS a signed, written attestation statement via email which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete.

We propose that, regardless of whether the eligible professional uses the XML or QRDA III format to report quality measures data to CMS, the qualified clinical data registry would be required to submit this data no later than the last Friday occurring 2 months after the end of the respective reporting period (that is, February 27, 2015 for reporting periods occurring in 2014). We also propose that, if a qualified clinical data registry is submitting quality measures data on behalf of individual eligible professionals that are part of the same group practice (but not participating in the PQRS GPRO), the qualified clinical data registry would have the option to report the quality measures data to CMS in a batch containing data for each of the individual eligible professionals within the group practice, rather than submitting individual files for each eligible professional.

In conjunction with our proposal to require that qualified clinical data registries be able to provide data on quality measures in a CMS-approved XML format, we propose to require that qualified clinical data registries report back to participants on the completeness, integrity, and accuracy of its participants' data. We believe that it would be beneficial to the participants to receive feedback on the data transmission process so that the participants are aware of any inaccuracies transmitted to CMS.

Alternatively, with respect to the information CMS would require a qualified clinical data registry to furnish to CMS to determine that the eligible professionals have met the criteria for satisfactory participation for the 2014 PQRS incentive and 2016 PQRS payment adjustment, in lieu of accepting quality measures data for reporting periods occurring in 2014 only, we considered proposing that a qualified clinical data registry provide CMS with a list of the eligible professionals (containing the respective eligible professionals' TIN/NPI information) who participated in and reported quality data to the qualified clinical data registry in order to determine which individual eligible professionals met the criteria for satisfactory participation for the 2014 PQRS incentive and 2016 PQRS payment adjustment. We considered this alternative because we do not have experience collecting data from qualified clinical data registries, we are unfamiliar with the type of quality data qualified clinical data registries collect, and we are still building out our data infrastructure.

We seek public comment on these proposals.

c. Proposed Process for Being Designated as a Qualified Clinical Data Registry

Section 1848(m)(3)(E)(v) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, requires the Secretary to establish a process to determine whether or not an entity meets the requirements established under section 1848(m)(3)(E)(i) of the Act. Such process may involve one or both of the following: (I) A determination by the Secretary; (II) A designation by the Secretary of one or more independent organizations to make such determination. This section sets forth our proposals for our process to determine whether or not an entity should be designated as a qualified clinical data registry.

Consistent with what we require of traditional qualified registries under the PQRS, we propose that an entity must submit a self-nomination statement that indicates its intent to participate in PQRS as a qualified clinical data registry. We believe this self-nomination statement is necessary for CMS to anticipate how many clinical data registries would participate for a certain year as well as provide information to eligible professionals about potential participating clinical data registries. We propose that the self-nomination statement contain the following information:

- The name of the entity seeking to become a qualified clinical data registry.
- The entity's contact information, including phone number, email, and mailing address.
- A point of contact, including the contact's email address and phone number, for which to notify the entity of the status of its request to be considered a qualified clinical data registry.
- The measure title, description, and specifications for each measure the qualified clinical data registry would require its eligible professionals to report for purposes of participating in PQRS. In addition, the qualified clinical data registry must describe the rationale and evidence basis to support each measure it would require its eligible professionals to report.
- The reporting period start date the entity will cover as a clinical data registry.

Since we believe that accepting these statements via email would be the most efficient method for collecting and processing self-nomination statements, we propose to accept self-nomination statements via email only. However, in the event that it is not technically feasible to collect this self-nomination statement via email, we propose that entities seeking to become qualified clinical data registries submit its self-nomination statement via a mailed letter to CMS. The self-nomination statement would be mailed to the following address: Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850.

To ensure that CMS is able to process these self-nomination statements as early as possible, we propose that these self-nomination statements must be received by CMS by 5:00 p.m. Eastern Standard Time on January 31 of the year in which the clinical data registry seeks to be qualified (that is, January 31, 2014 for purposes of becoming a qualified clinical data registry for the reporting periods for the 2014 PQRS incentive and 2016 PQRS payment adjustment). We understand that this is an early proposed deadline, particularly since this is a new reporting mechanism. However, it is necessary for us to propose a deadline of January 31 to ensure that we have sufficient time to analyze the self-nomination statements we receive, ensure that the entity meets the basic requirements for being designated as a qualified clinical data

registry, including whether or not the quality measures the entity intends to report on behalf of eligible professionals meet the requirements set forth in section I.11 of this proposed rule, and allow for sufficient time for eligible professionals to view a list of entities that are qualified as clinical data registries for the year prior to the end of the applicable reporting period for satisfactory participation in a qualified clinical data registry. We anticipate posting a list of the entities that are designated by CMS as qualified clinical data registries in the Fall of the same year.

Since participation in a qualified clinical data registry is a new option for individual eligible professionals, we anticipate making changes to the requirements for becoming a qualified clinical data registry in future rulemaking as we gain more experience with this option. Since we believe it is important that the entity keep up with these changes, at this time, we propose that entities seeking to serve as qualified clinical data registries must self-nominate for each year that the entity seeks to participate. In the future, we anticipate moving towards a 2-year self-nomination process as the requirements for qualified clinical data registries become firmly established; however, at this time, we are proposing self-nomination for any year in which a qualified clinical data registry intends to participate under the PQRS.

We seek public comment on these proposals.

d. Proposed Reporting Period for the Satisfactory Participation by Individual Eligible Professionals in a Qualified Clinical Data Registry for the 2014 PQRS Incentive

Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the America Taxpayer Relief Act of 2012, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(A) of the Act if the eligible professional is satisfactorily participating in a qualified clinical data registry for the year. Given that satisfactory participation is with regard to the year, and to provide consistency with the reporting period applicable to individual eligible professionals who report quality measures data under section 1848(m)(3)(A), we propose to modify § 414.90(c)(5) to specify a 12-month, calendar year (CY) reporting period from January 1, 2014 through December 31, 2014 for individual eligible professionals to satisfactorily participate in a qualified clinical data registry for purposes of the 2014 PQRS incentive. We are proposing a 12-month reporting period. Based on our experience with the 12 and 6-month reporting periods for the PQRS incentives, we believe that data on quality measures collected based on 12-months provides a more accurate assessment of actions performed in a clinical setting than data collected based on shorter reporting periods. In addition, we believe a 12-month reporting period is appropriate given that the full calendar year would be utilized with regard to the participation by the individual eligible professional in the qualified clinical data registry. We invite public comment on the proposed 12-month, CY 2014 reporting period for the satisfactory participation of individual eligible professionals in a qualified clinical data registry for the 2014 PQRS incentive.

e. Proposed Criteria for Satisfactory Participation for Individual Eligible Professionals in a Qualified Clinical Data Registry for the 2014 PQRS Incentive

For 2014, in accordance with § 414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the America Taxpayer Relief Act of 2012, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(A) of the Act if, in lieu of reporting measures under section 1848(k)(2)(C) of the Act, the eligible professional is satisfactorily participating in a qualified clinical data registry for the year. ''Satisfactory participation'' is a new standard under the PQRS and is a substitute for the underlying standard of ''satisfactory reporting'' data on covered professional services that eligible professionals must meet to earn a PQRS incentive or avoid the PQRS payment adjustment. Therefore, we propose to modify § 414.90 to add paragraph (c)(5) to indicate that individual eligible professionals shall be treated as satisfactorily reporting data on quality measures if individual eligible professionals satisfactorily participate in a qualified clinical data registry for purposes of the PQRS incentive. This section also contains the criterion we are proposing for individual eligible professionals to meet to satisfactorily participate in a qualified clinical data registry for purposes of the 2014 PQRS incentive.

We understand that qualified clinical data registries may have different ways to measure success in quality reporting among its registry participants. However, for purposes of the 2014 PQRS incentive, CMS must establish a standard for satisfactory participation in a qualified clinical data registry. Therefore, we propose that, to meet the criteria for satisfactory participation for the 2014 PQRS incentive, an individual eligible professional would be required to: For the 12-month 2014 reporting period, report at least 9 measures available for reporting under the qualified clinical data registry covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the eligible professional's applicable patients. Of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure. We further propose that a qualified clinical data registry may submit data on more than 9 quality measures on behalf on an eligible professional. However, we propose that a qualified clinical data registry may not submit data on more than 20 measures on behalf of an eligible professional. We propose to place a limit on the number of measures that a qualified clinical data registry may submit on behalf of an eligible professional at this time because we have no experience with qualified clinical data registries and the types of data on quality measures that they collect.

We note that this proposed criterion for satisfactory participation is consistent with proposed requirements set forth (for example, the reporting period as well as the number of individual measures, domains, and applicable patients proposed to be reported) for meeting the criteria for the satisfactory reporting of individual PQRS quality measures using the traditional claims, registry, and EHR-based reporting mechanisms for the 2014 PQRS incentive (for example, the reporting period as well as the number of individual measures, domains, and applicable patients proposed to be reported). We believe it is important to propose a similar quality data reporting criterion for individual eligible professionals to satisfactorily participate in a qualified clinical data registry as for satisfactory reporting for the 2014 PQRS incentive so that this proposed satisfactory participation option to

satisfy the PQRS is not disproportionately more advantageous or less burdensome than the other proposed criteria for satisfactory reporting for the 2014 PQRS incentive. However, this proposed criterion for satisfactory participation departs from the proposed criteria for satisfactory reporting for the 2014 PQRS incentive in a number of ways. First, an eligible professional using a qualified clinical data registry is required to report on at least 1 outcome measure. Second, whereas the proposed criteria for satisfactory reporting on individual PQRS quality measures require the reporting of at least 1 Medicare Part B FFS patient, this proposed criterion for satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive would not require reporting on Medicare patients. Please note that because we are also proposing more stringent requirements for an entity to become a qualified clinical data registry than a traditional qualified registry, such as requiring benchmarking capacity, we believe that individual eligible professionals who participate in a qualified clinical data registry would be doing more than just reporting quality data to the qualified data registry for PQRS purposes. Over time, as we gain more experience with the capabilities of qualified clinical data registries, we anticipate that the criteria for satisfactory participation will further depart from the criteria for satisfactory reporting under PQRS and incorporate other quality improvement functions that may be provided by a qualified clinical data registry to its participants as this option evolves.

We seek public comment on the proposed criterion for the satisfactory participation by individual eligible professionals in a qualified clinical data registry for the 2014 PQRS incentive.

f. Proposed Reporting Period for the Satisfactory Participation for Individual Eligible Professionals in a Qualified Clinical Data Registry for the 2016 PQRS Payment Adjustment

Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the American Tax Relief Act of 2012, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(A) of the Act if the eligible professional is satisfactorily participating in a qualified clinical data registry for the year. Given that satisfactory participation is with regard to the year, and to provide consistency with how individual eligible professionals report quality measures data to a qualified clinical data registry, we propose to modify § 414.90(e)(2) to specify a 12-month, calendar year (CY) reporting period from January 1, 2014 through December 31, 2014, for individual eligible professionals to satisfactorily participate in a qualified clinical data registry for purposes of the 2016 PQRS payment adjustment. We are proposing a 12-month reporting period because, based on our experience with the 12 and 6-month reporting periods for the PQRS incentives, we believe that data on quality measures collected based on 12-months provides a more accurate assessment of actions performed in a clinical setting than data collected based on shorter reporting period. We also believe that a 12-month reporting period is appropriate given that the full calendar year would be utilized with regard to the participation by the individual eligible professional in the qualified clinical data registry.

We are proposing a 12-month reporting period occurring 2 years prior to the application of the 2016 PQRS payment adjustment for individual eligible professionals to allow time to perform all reporting analyses, and make determinations about whether the individual eligible professional satisfactorily participated in a qualified clinical data registry, prior to applying payment adjustments on eligible professionals' Medicare Part B PFS claims in 2016. However, in future years, we may propose alternative reporting periods that could occur closer in time to the application of the PQRS payment adjustment. We invite public comment on the proposed 12-month, CY 2014 reporting period (that is, January 1, 2014–December 31, 2014) for the satisfactory participation of individual eligible professionals in a qualified clinical data registry for the 2016 PQRS payment adjustment.

g. Proposed Criteria for the Satisfactory Participation for Individual Eligible Professionals in a Qualified Clinical Data Registry for the 2016 PQRS Payment Adjustment

Section 1848(a)(8) of the Act provides that for covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the American Tax Relief Act of 2012, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(A) of the Act if, in lieu of reporting measures under section 1848(k)(2)(C) of the Act, the eligible professional is satisfactorily participating in a qualified clinical data registry for the year. ''Satisfactory participation'' is a new standard under the PQRS and is a substitute for the underlying standard of ''satisfactory reporting'' data on covered professional services that eligible professionals must meet to earn a PQRS incentive or avoid the PQRS payment adjustment. Therefore, we propose to modify § 414.90 to add paragraph (e)(2) to indicate that individual eligible professionals shall be treated as satisfactorily reporting data on quality measures, if the individual eligible professional satisfactorily participates in a qualified clinical data registry. This section also contains the criterion we are proposing for individual eligible professionals to meet to satisfactorily participate in a qualified clinical data registry for purposes of the 2016 PQRS payment adjustment.

We propose that, for purposes of the 2016 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2014), the exact same requirement we proposed above for satisfactory participation for the 2014 PQRS incentive. We believe it is appropriate to propose identical criteria for meeting the new standard for satisfactory participation given that the proposed 12-month reporting period for satisfactory participation in a qualified clinical data registry for the respective 2014 PQRS incentive and 2016 PQRS payment adjustments coincide.

We seek public comment on the proposed criterion for the satisfactory participation by individual eligible professionals in a qualified clinical data registry for the 2016 PQRS payment adjustment.

Tables 24 and 25 provide a summary of the proposed criteria for satisfactory reporting and satisfactory participation we discussed above for individual eligible professionals for the 2014 PQRS incentive and 2016 PQRS payment adjustment respectively.

TABLE 24—SUMMARY OF PROPOSALS FOR THE 2014 PQRS INCENTIVE: PROPOSED CRITERIA FOR SATISFACTORY REPORTING OF INDIVIDUAL QUALITY MEASURES VIA CLAIMS AND REGISTRIES AND PROPOSED SATISFACTORY PARTICIPATION CRITERION FOR INDIVIDUAL ELIGIBLE PROFESSIONALS IN QUALIFIED CLINICAL DATA REGISTRIES

Reporting period	Measure type	Reporting mechanism	Proposed satisfactory reporting criteria and satisfactory participation criteria
12-month (Jan 1–Dec 31) ...	Individual Measures	* Claims	Report at least 9 measures covering at least 3 of the National Quality Strategy domains, OR, If less than 9 measures apply to the eligible professional, then the eligible professional must report 1–8 measures for which there is Medicare patient data; and Report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31) ...	Individual Measures	Qualified Registry	Report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31) ...	Measures selected by Qualified Clinical Data Registry.	Qualified Clinical Data Registry.	Report at least 9 measures available for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50% of the eligible professional's patients. Of the measures reported via a clinical data registry, the eligible professional must report on at least 1 outcome measure.

*Subject to the MAV process.

TABLE 25—SUMMARY OF PROPOSALS FOR THE 2016 PQRS PAYMENT ADJUSTMENT: PROPOSED CRITERIA FOR SATISFACTORY REPORTING OF INDIVIDUAL QUALITY MEASURES VIA CLAIMS AND REGISTRIES AND PROPOSED SATISFACTORY PARTICIPATION CRITERION FOR INDIVIDUAL ELIGIBLE PROFESSIONALS IN QUALIFIED CLINICAL DATA REGISTRIES

Reporting period	Measure type	Reporting mechanism	Proposed satisfactory reporting and participation criteria
12-month (Jan 1–Dec 31) ...	Individual Measures	*Claims	Report at least 9 measures covering at least 3 of the National Quality Strategy domains, OR, If less than 9 measures apply to the eligible professional, then the eligible professional must report 1–8 measures for which there is Medicare patient data; and Report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies.
12-month (Jan 1–Dec 31) ...	Individual Measures	Registry	Report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31) ...	Measures selected by the Qualified Clinical Data Registry.	Qualified Clinical Data Registry.	Report at least 9 measures available for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the eligible professional's patients. Of the measures reported via a clinical data registry, the eligible professional must report on at least 1 outcome measure.

*Subject to the MAV process.

7. Proposed Criteria for Satisfactory Reporting for the 2014 PQRS Incentive for Group Practices in the GPRO

For 2014, in accordance with § 414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. We finalized criteria for the satisfactory reporting for group practices participating in the GPRO for the 2014 PQRS incentive in the CY 2013 PFS final rule with comment period (see

Table 93, 77 FR 69195). In this section, we propose to change some of the criteria for satisfactory reporting for group practices under the GPRO using the registry and GPRO Web interface reporting mechanisms.

Group practices may currently report PQRS quality measures data to meet the criteria for satisfactory reporting for the 2014 PQRS incentive via the registry, EHR, and GPRO web interface reporting mechanisms. For the 2014 PQRS incentive, we finalized the following criterion for the satisfactory reporting of PQRS quality measures via the GPRO web interface for group practices comprised of 25–99 eligible professionals: Report on all measures included in the web interface; and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries (77 FR 69195). We established this same criterion for the group practices of 25–99 eligible professionals for the 2013 PQRS incentive. Unfortunately, there has been low participation for this reporting option. We believe this is due to the fact that reporting using the GPRO web interface is more beneficial to larger practices because larger practices are better able to report on a more varied patient population. Therefore, to streamline the PQRS and eliminate reporting options that are largely unused, we propose to eliminate this criterion under the GPRO for the 2014 PQRS incentive. As a result, group practices comprised of 25–99 eligible professionals would no longer have the option to report PQRS quality measures using the GPRO web interface for the 2014 PQRS incentive. We do not believe this harms these smaller groups' practices, as group practices in the GPRO would still be able to report PQRS quality measures using either the registry or EHR-based reporting mechanisms.

For reporting under the GPRO using the registry-based reporting mechanism, we finalized the following criterion for the satisfactory reporting of PQRS quality measures for group practices comprised of 2 or more eligible professionals for the 2014 PQRS incentive in the CY 2013 final rule with comment period: Report at least 3 measures, and report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (77 FR 69196). For the same reasons we are proposing to increase the number of measures an individual eligible must report as well as decrease the percentage threshold for individual eligible professionals reporting via registry for the 2014 PQRS incentive, we propose the following modified criteria for the satisfactory reporting of individual quality measures under the GPRO for the registry-based reporting mechanism: Report at least 9 measures covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50% of the group practice's applicable seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.

In addition, patient surveys are important tools for assessing beneficiary experience of care and outcomes. Many surveys are being used in both the private and public sectors, including the Medicare Health Outcomes Survey used by Medicare Advantage (MA) plans, Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey tools, and Health Resources Services Administration's (HRSA's) Health Center Patient Satisfaction Survey. Over the past two years, we have developed a Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey for use with the Medicare Shared Savings Program and the PQRS. In 2012, we field tested the survey with a sample of 6,750 Medicare Fee-for-Service beneficiaries receiving care from nine group practices that participated in the Physician Group Practice Transition Demonstration. Subsequent to the field test, we refined the survey and in the spring of 2013 administered it for all Accountable Care Organizations (ACOs) participating in the Pioneer ACO program and the Medicare Shared Savings Program during 2012. More information about the survey is available at the **Federal Register** (77 FR 73032 and 78 FR 17676).

Because we believe these patient surveys are important tools for assessing beneficiary experience of care and outcomes, under our authority under section 1848(m)(3)(C)(i) of the Act to select the measures for which a group practice must report, we propose to provide group practices comprised of 25 or more eligible professionals with a new satisfactory reporting criterion that would include the option to complete the CG CAHPS survey along with reporting 6 other PQRS measures for purposes of meeting the criteria for satisfactory reporting for the 2014 PQRS incentive and 2016 PQRS payment adjustment.

We further propose that the survey would be administered following the close of the PQRS registration period. CMS also would provide each group a detailed report about the results of the survey. In addition, we propose to assign beneficiaries to a group practice using the same assignment methodology that we use for the GPRO web interface (77 FR 69195) . This method focuses on assigning beneficiaries to a group based on whether the group provided the plurality of primary care services. Because we propose to assign beneficiaries to a group based on the provision of primary care services, this survey is not an appropriate option for groups of physicians (for example, such as a group of surgeons) that do not provide primary care services. In accordance with section 1848(m)(3)(C)(ii) of the Act, which requires the GPRO to provide for the use of a statistical sampling model, we propose that the survey would be administered by certified survey vendor on behalf of the group practice for a sample of group's assigned beneficiaries. As noted earlier, to complete this survey, a group practice must indicate its intent to report the CG CAHPS survey when it registers to participate in the PQRS via the GPRO.

Please note that the CAHPS survey measures only cover 1 National Quality Strategy domain. In order to be consistent with other group practice reporting criteria we are proposing that require the reporting of measures covering at least 3 National Quality Strategy domains, we are proposing that, if a group practice reports the CAHPS measures via a certified survey vendor, the group practice would be required to report on at least 6 additional measures covering at least 2 National Quality Strategy domains.

Specifically, we are proposing the following criteria for satisfactory reporting for the 2014 PQRS incentive: For the 12-month reporting period for the 2014 PQRS incentive, report all CAHPS survey measures via a certified vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms.

We seek public comment on our proposed criterion for the satisfactory reporting of data on these PQRS quality measures under the GPRO for the 2014 PQRS incentive.

8. Criteria for Satisfactory Reporting for the 2016 PQRS Payment Adjustment for Group Practices in the GPRO

This section addresses the proposed criteria for satisfactory reporting for group practices in the GPRO for the 2016 PQRS payment adjustment using the registry, GPRO web interface, and certified survey vendor reporting mechanisms. In the CY 2013 PFS final rule with comment period, we finalized the same criteria for satisfactorily reporting data on quality measures for the 2016 PQRS payment adjustment that apply for the 2014 PQRS incentive for the PQRS GPRO (77 FR 69200). We are making three of the same proposals for the criteria for satisfactory reporting under the GPRO for the 2016 PQRS payment adjustment that we are proposing for the 2014 PQRS incentive. Specifically, we propose to eliminate the following criterion for satisfactory reporting of PQRS quality measures via the GPRO web interface for group practices comprised of 25–99 eligible professionals: Report on all measures included in the web interface; and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries. For the same reasons discussed previously and to maintain consistent criteria for the 2016 PQRS payment adjustment and 2014 PQRS incentive, we believe this proposed change is appropriate. We also note that if this proposal is finalized, only groups of 100 or more eligible professionals would be able to use the web interface reporting mechanism to report quality data under the GPRO.

Second, we propose to remove the following criterion for satisfactory reporting via registry under the GPRO for the 2016 PQRS payment adjustment: Report at least 3 measures, and report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted. This would allow us to maintain consistent criteria for the 2016 PQRS payment adjustment and 2014 PQRS incentive.

Consistent with our proposal to provide group practices comprised of 25 or more eligible professionals with a new satisfactory reporting criterion that would include the option to complete the CG CAHPS survey along with reporting 6 other PQRS measures for purposes of meeting the criteria for satisfactory reporting for the 2014 PQRS incentive, we also propose the same criterion for purposes of meeting the criteria for satisfactory reporting for the 2016 PQRS payment adjustment. Specifically, we are proposing the following criteria for satisfactory reporting for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2016 PQRS payment adjustment, report all CAHPS survey measures via a certified vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms. As noted earlier, to complete this survey, a group practice must indicate its intent to report the CG CAHPS survey when it registers to participate in the PQRS via the GPRO.

In addition, we are proposing the same criteria for satisfactory reporting of individual quality measures under the GPRO for the registry-based reporting mechanism for the 2016 PQRS payment adjustment that we proposed above for the 2014 PQRS Incentive: Report at least 9 measures covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the group practice's applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted. In addition to the reasons we noted previously for modifying the existing registry satisfactory reporting criterion to increase the number of measures reported from 3 to 9, we believe it is appropriate to continue to align, as closely as possible, the criteria for satisfactory reporting for both the 2016 PQRS payment adjustment and 2014 PQRS Incentive.

We note that the criteria for satisfactory reporting under the GPRO for the 2014 PQRS incentive and the 2016 PQRS payment adjustment would align (such that a group practice would avoid the 2016 PQRS payment adjustment by meeting any of the criteria for satisfactory reporting adopted for the 2014 PQRS incentive for the 12-month reporting period). We believe this is appropriate since the reporting period for the 2014 PQRS incentive and 2016 PQRS payment adjustment coincide. We seek public comment on these proposals as well as on whether we should offer alternative criteria for group practices participating in the PQRS GPRO to satisfy the 2016 PQRS payment adjustment similar to what we have established for individual eligible professionals reporting via claims.

Tables 26 and 27 provides a summary of our proposed criteria for the satisfactory reporting of data on PQRS quality measures via the GPRO for the 2014 PQRS incentive and 2016 PQRS payment adjustment.

TABLE 26—SUMMARY OF PROPOSALS FOR THE 2014 PQRS INCENTIVE: PROPOSED CRITERIA FOR SATISFACTORY REPORTING OF DATA ON PQRS QUALITY MEASURES VIA THE GPRO

Reporting period	Reporting mechanism	Group practice size	Proposed reporting criteria
12-month (Jan 1–Dec 31) ...	Qualified Registry	2 + eligible professionals ..	Report at least 9 measures covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the group practice's applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1–Dec 31) ...	Certified Survey Vendor + Qualified Registry, direct EHR product, EHR data submission vendor, or GPRO web interface.	25+ eligible professionals ..	Report all CG CAHPS survey measures via certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms.

TABLE 27—SUMMARY OF PROPOSALS FOR THE 2016 PQRS PAYMENT ADJUSTMENT: PROPOSED CRITERIA FOR SATISFACTORY REPORTING OF DATA ON PQRS QUALITY MEASURES VIA THE GPRO

Reporting period	Reporting mechanism	Group practice size	Proposed reporting criteria
12-month (Jan 1–Dec 31) ...	Qualified Registry	2 + eligible professionals ..	Report at least 9 measures covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the group practice's applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1–Dec 31) ...	Certified Survey Vendor + Qualified Registry, direct EHR product, EHR data submission vendor, or GPRO web interface.	25+ eligible professionals ..	Report all CG CAHPS survey measures via certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms.

9. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Reporting for 2013 and Beyond for Individual Eligible Professionals and Group Practices

CMS undergoes an annual Call for Measures that solicits new measures from the public for possible inclusion in the PQRS for 2014 and beyond. During the Call for Measures, we request measures for inclusion in PQRS that meet the following statutory and non-statutory criteria.

Sections 1848(k)(2)(C) and 1848(m)(3)(C)(i) of the Act, respectively, govern the quality measures reported by individual eligible professionals and group practices reporting under the PQRS. Under section 1848(k)(2)(C)(i) of the Act, the PQRS quality measures shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (currently, that is the National Quality Forum, or NQF). However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the NQF, section 1848(k)(2)(C)(ii) of the Act authorizes the Secretary to specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary, such as the AQA alliance. In light of these statutory requirements, we believe that, except in the circumstances specified in the statute, each PQRS quality measure must be endorsed by the NQF. Additionally, section 1848(k)(2)(D) of the Act requires that for each PQRS quality measure, ''the Secretary shall ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish.''

The statutory requirements under section 1848(k)(2)(C) of the Act, subject to the exception noted previously, require only that the measures be selected from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) (that is, the NQF) and are silent for how the measures that are submitted to the NQF for endorsement were developed. The basic steps for developing measures applicable to physicians and other eligible professionals prior to submission of the measures for endorsement may be carried out by a variety of different organizations. We do not believe there needs to be any special restrictions on the type or make-up of the organizations carrying out this basic process of development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the basic development of quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards for purposes of the PQRS.

In addition to section 1848(k)(2)(C) of the Act, section 1890A of the Act, which was added by section 3014(b) of the Affordable Care Act, requires that the entity with a contract with the Secretary under subsection 1890(a) of the Act (currently that, is the NQF) convene multi-stakeholder groups to provide input to the Secretary on the selection of certain categories of quality and efficiency measures. These categories are described in section 1890(b)(7)(B) of the Act, and include such measures as the quality measures selected for reporting under the PQRS. Pursuant to section 3014 of Affordable Care Act, the NQF convened multi-stakeholder groups by creating the Measure Applications Partnership (MAP). Section 1890(A)(a) of the Act requires that the Secretary establish a pre-rulemaking process in which the Secretary must make publicly available by December 1st of each year a list of the quality and efficiency measures that the Secretary is considering for selection through rulemaking for use in the Medicare program. The NQF must provide CMS with the MAP's input on selecting measures by February 1st of each year. The list of measures under consideration for 2013 is available at *http://www.qualityforum.org/map/*.

As we noted above, section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). We may select measures under this exception if there is a specified area or medical topic for which a feasible and practical measure has not been endorsed by the entity, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Under this exception, aside from NQF endorsement, we requested that stakeholders apply the following considerations when submitting measures for possible inclusion in the PQRS measure set:

- High impact on healthcare.
- Measures that are high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.
- Measures that address gaps in the quality of care delivered to Medicare beneficiaries.
- Address Gaps in the PQRS measure set.
- Measures impacting chronic conditions (chronic kidney disease, diabetes mellitus, heart failure, hypertension and musculoskeletal).

• Measures applicable across care settings (such as, outpatient, nursing facilities, domiciliary, etc.).
• Broadly applicable measures that could be used to create a core measure set required of all participating eligible professionals.
• Measures groups that reflect the services furnished to beneficiaries by a particular specialty.

10. Proposed PQRS Quality Measures

Taking into consideration the statutory and non-statutory criteria we described previously, this section contains our proposals for the inclusion or removal of measures in PQRS for 2014 and beyond. We are classifying all proposed measures against six domains based on the National Quality Strategy's six priorities, as follows:

(1) *Person and Caregiver-Centered Experience and Outcomes.* These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level as well as the population level through greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.

(2) *Patient Safety.* These are measures that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.

(3) Communication and *Care Coordination.* These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve appropriate and timely patient and care team communication.

(4) *Community/Population Health.* These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.

(5) *Efficiency and Cost Reduction.* These are measures that reflect efforts to significantly improve outcomes and reduce errors. These measures also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.

(6) *Effective Clinical Care.* These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

Please note that the PQRS quality measure specifications for any given proposed PQRS individual quality measure may differ from specifications for the same quality measure used in prior years. For example, for the proposed PQRS quality measures that were selected for reporting in 2013 and beyond, please note that detailed measure specifications, including the measure's title, for the proposed individual PQRS quality measures for 2013 and beyond may have been updated or modified during the NQF endorsement process or for other reasons. In addition, due to our desire to align measure titles with the measure titles that were proposed for 2013, 2014, 2015, and potentially subsequent years of the EHR Incentive Program, we note that the measure titles for measures available for reporting via EHR may change. To the extent that the EHR Incentive Program updates its measure titles to include version numbers (77 FR 13744), we intend to use these version numbers to describe the PQRS EHR measures that will also be available for reporting for the EHR Incentive Program. We will continue to work toward complete alignment of measure specifications across programs whenever possible.

Through NQF's measure maintenance process, NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantively change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In the CY 2013 PFS final rule with comment period, we finalized our proposal providing that if the NQF updates an endorsed measure that we have adopted for the PQRS in a manner that we consider to not substantively change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program (77 FR 69207). We believe this adequately balances our need to incorporate non-substantive NQF updates to NQF-endorsed measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. We will revise the Specifications Manual and post notices to clearly identify the updates and provide links to where additional information on the updates can be found. Updates will also be available on the CMS PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*.

With respect to the PQRS EHR measures that are also reportable under the EHR Incentive Program (i.e., electronically specified clinical quality measures), please note that the updates to these measures will be provided on the EHR Incentive Program Web site. We understand that the EHR Incentive Program may accept versions of electronically specified clinical quality measures that may be outdated. We propose that for purposes of the PQRS, eligible professionals must report the most recent, updated version of a clinical quality measure. For example, for purposes of reporting clinical quality measures that are electronically specified during the PQRS reporting periods that occur in 2014, we would only accept the reporting of clinical quality measures that are electronically specified using versions of the electronic specifications that were updated and posted on June 2013, available at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*. We also understand, for purposes of the EHR Incentive Program, that once direct EHR products and EHR data submission vendors are issued a 2014 Edition certification for clinical quality measures, they will not necessarily be required to have such technology retested and recertified against the most recent, updated version of a clinical quality measure when such versions are made available. We propose that for purposes of PQRS, however, that the eligible professional's direct EHR product or EHR data submission vendor must be tested and certified to the most recent, updated version of an electronically specified clinical quality

measure. For example, for purposes of reporting clinical quality measures that are electronically specified during the PQRS reporting periods that occur in 2014, we would only accept the reporting of clinical quality measures from direct EHR products or EHR data submission vendors that have been tested and certified to versions of the electronic specifications that were updated and posted on June 2013. We seek comment on our proposals to require eligible professionals to both use the most recent, updated version of an electronically specified clinical quality measure to report for PQRS and to use a direct EHR product or EHR data submission vendor that has been tested and certified to the most recent, updated version of the clinical quality measure's electronic specifications for PQRS purposes.

a. Proposed Individual PQRS Measures and Measures Within Measures Groups Available for Reporting for 2014 and Beyond

(1) Proposed PQRS Core Measures Available for Reporting for 2014 and Beyond

In the CY 2013 PFS final rule with comment period, we finalized the HHS Million Hearts Measures as a recommended set of core measures for which we encourage eligible professionals to report in PQRS (77 FR 69209). In addition to the HHS Million Hearts Measures we previously finalized, we are proposing to include the measures specified in Table 28 as additional recommended core measures for 2014 and beyond (in the table we also identify the applicable PQRS reporting mechanism through which each measure could be submitted). These additional proposed recommended core measures were also finalized as recommended core measures in the EHR Incentive Program for 2014. Therefore, due to our desire to align with the recommended measures available under the EHR Incentive Program, we are proposing the additional recommended measures specified in Table 28 for 2014 and beyond.

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TABLE 28: Proposed Physician Quality Reporting System Recommended Core Measures for 2014 and Beyond

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0002/66**	146v2	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children aged 2 through 18 years with a diagnosis of pharyngitis, who were prescribed an antibiotic and who received a group A streptococcus (strep) test for the episode. A higher rate represents better performance (i.e. appropriate testing).	NCQA		X	X			MU2
0018/236*	165v2	Effective Clinical Care	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg)	NCQA	X	X	X	X	X	MU2 ACO Million Hearts
0022/238*	156v2	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two different high-risk medications.	NCQA			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0024/239**	155v2	Community/ Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. - Percentage of patients with height, weight, and body mass index (BMI) percentile documentation - Percentage of patients with counseling for nutrition - Percentage of patients with counseling for physical activity	NCQA			X			MU2
0028/226*	138v2	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI	X	X	X	X	X	MU2 ACO Million Hearts
0033/310**	153v2	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women aged 15 through 24 years who were identified as sexually active and who had at least one test for chlamydia during the measurement year	NCQA			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0036/311**	126v2	Effective Clinical Care	**Use of Appropriate Medications for Asthma:** Percentage of patients aged 5 through 50 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement year	NCQA			X			MU2
0038/240**	117v2	Community/ Population Health	**Childhood Immunization Status:** The percentage of children two years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV); one measles, mumps, rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); two hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday	NCQA			X			MU2
0052/312*	166v2	Efficiency and Cost Reduction	**Use of Imaging Studies for Low Back Pain:** Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis.	NCQA			X			MU2
0069/65**	154v2	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months-18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	NCQA		X	X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0108/N/A**	136v3	Effective Clinical Care	**ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication:** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	NCQA			X			MU2
0418/134***	2v2	Community/ Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	CMS	X	X	X	X		MU2 ACO

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0419/130*	68v2	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS	X	X	X		X	MU2
0421/128*	69v1	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**. **Normal Parameters:** Age 65 years and older BMI ≥ 23 and < 30; Age 18 – 64 years BMI ≥ 18.5 and < 25	CMS	X	X	X	X	X	MU2 ACO
N/A/N/A**	75v2	Effective Clinical Care	**Children who have dental decay or cavities:** Percentage of children ages, 0-20 years, who have had tooth decay or cavities during the measurement period	CMS			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A*	50v2	Communication and Care Coordination	**Closing the referral loop: receipt of specialist report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred	CMS			X			MU2
N/A/N/A*	90v3	Person and Caregiver-Centered Experience and Outcomes	**Functional status assessment for complex chronic conditions:** Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments	NQF			X			MU2

* Recommended Adult Core CQMs for eligible professionals

** Recommended Pediatric Core CQMs for eligible professionals

¥ Titles and descriptions in this table are aligned with the 2014 Physician Quality Reporting System Claims and Qualified Registry measure titles and descriptions, and may differ from existing measures in other programs. When reporting data on these measures, please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

(2) Proposed Individual PQRS Measures Available for Reporting for 2014 and Beyond

Table 29 contains the measures we are proposing to include in the PQRS measure set for 2014 and beyond. Please note that our rationale for proposing each of these measures is found below the measure description. We have also indicated the PQRS reporting mechanism or mechanisms through which each proposed measure could be submitted.

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TABLE 29: Proposed Individual Quality Measures and Those Included in Measures Groups for the Physician Quality Reporting System to be Available for Satisfactory Reporting via Claims, Registry, or EHR Beginning in 2014

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0060/N/A	148v2	Effective Clinical Care	**Hemoglobin A1c Test for Pediatric Patients:** Percentage of patients 5-17 years of age with diabetes with an HbA1c test during the measurement period **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. Furthermore, including this measure in the PQRS measure set is in accordance with our intention to align with the measures included in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	NCQA			X			MU2
0108/N/A	136v3	Effective Clinical Care	**ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication:** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. We are proposing this measure for inclusion in PQRS because this measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	NCQA			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0403/N/A	62v2	Efficiency and Cost Reduction	**HIV/AIDS: Medical Visit:** Percentage of patients, regardless of age, with a diagnosis of HIV/AIDS with at least two medical visits during the measurement year with a minimum of 90 days between each visit **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. We are proposing this measure for inclusion in PQRS because this measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	NCQA			X			MU2
0110/N/A	169v1	Effective Clinical Care	**Bipolar Disorder and Major Depression: Appraisal for Alcohol or Chemical Substance Use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CQAIMH			X			MU2
0608/N/A	158v2	Effective Clinical Care	**Pregnant Women that had HBsAg Testing:** This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	OptumInsight			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0710/N/A	159v2	Effective Clinical Care	**Depression Remission at Twelve Months:** Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at twelve months defined as PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	MNCM			X			MU2
0712/N/A	160v2	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** Adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a PHQ-9 tool administered at least once during a 4 month period in which there was a qualifying visit **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	MNCM			X			MU2
1401/N/A	82v1	Community/ Population Health	**Maternal Depression Screening:** The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	NCQA			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	65v3	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2
N/A/N/A	50v2	Communication and Care Coordination	**Closing the referral loop: receipt of specialist report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	66v2	Effective Clinical Care	**Functional Status Assessment for Knee Replacement:** Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2
N/A/N/A	56v2	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Hip Replacement:** Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	90v3	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Complex Chronic Conditions:** Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2
N/A/N/A	75v2	Effective Clinical Care	**Children Who Have Dental Decay or Cavities:** Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	74v3	Effective Clinical Care	**Primary Caries Prevention Intervention as offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2
N/A/N/A	179v2	Patient Safety	**ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range:** Average percentage of time in which patients aged 18 and older with atrial fibrillation who are on chronic warfarin therapy have International Normalized Ratio (INR) test results within the therapeutic range (i.e., TTR) during the measurement period **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
1365/N/A	177v2	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	AMA-PCPI			X			MU2
N/A/N/A	77v2	Effective Clinical Care	**HIV/AIDS: RNA Control for Patients with HIV:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 90 days between each visit, whose most recent HIV RNA level is <200 copies/mL **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2
2082/N/A		Effective Clinical Care	**HIV Viral Load Suppression:** Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year. **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program. It aligns to current clinical standards for treatment for patient with the chronic condition of HIV.	HRSA		X			X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
2083/N/A		Effective Clinical Care	**Prescription of HIV Antiretroviral Therapy:** Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program. It aligns to current clinical standards for treatment for patient with the chronic condition of HIV.	HRSA		X			X	
2079/N/A		Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is in alignment with the HHS/HRSA strategy for having a core set of HIV measures.	HRSA					X	
2080/N/A		Efficiency and Cost Reduction	**Gap in HIV medical visits:** Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 month of the measurement year **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is in alignment with the HHS/HRSA strategy for having a core set of HIV measures.	HRSA					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate Measure:** The percentage of patients age 50 years or older with at least one adenoma or other colorectal cancer precursor or colorectal cancer detected during screening colonoscopy **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure addresses a broad patient population for screening and detection of colorectal cancer and is medically significant in the measurement of utilizing preventive healthcare services. The individual measure is reportable for Gastroenterologist and other eligible professionals within this scope of practice. Currently, PQRS has 2 specific measures that are applicable to this scope of practice.	ACGAGA/ ASGE		X				
N/A/N/A		Communication and Care Coordination	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. NSAIDs, analgesics, exercise, injections) prior to the procedure **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is contained within the Total Knee Replacement Measures Group. This measures group provides eligible professionals opportunity to report assessments prior to a total knee surgery such as shared decision-making reviewing conservative therapy prior to invasive surgery, risk assessment, prophylactic antibiotic prior to tourniquet inflation, and identification of prosthesis implant within medical chart. This measures group allows Orthopedic Surgeons and other eligible professionals within this scope of practice a measures group to report.	AAHKS/ AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including history of deep vein thrombosis (DVT), pulmonary embolism (PE), myocardial infarction (MI), arrhythmia and stroke **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is contained within the Total Knee Replacement Measures Group. This measures group provides eligible professionals opportunity to report assessments prior to a total knee surgery such as shared decision-making reviewing conservative therapy prior to invasive surgery, risk assessment, prophylactic antibiotic prior to tourniquet inflation, and identification of prosthesis implant within medical chart. This measures group allows Orthopedic Surgeons and other eligible professionals within this scope of practice a measures group to report.	AAHKS/ AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is contained within the Total Knee Replacement Measures Group. This measures group provides eligible professionals opportunity to report assessments prior to a total knee surgery such as shared decision-making reviewing conservative therapy prior to invasive surgery, risk assessment, prophylactic antibiotic prior to tourniquet inflation, and identification of prosthesis implant within medical chart. This measures group allows Orthopedic Surgeons and other eligible professionals within this scope of practice a measures group to report.	AAHKS/ AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of prosthetic implant and the size of prosthetic implant **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is contained within the Total Knee Replacement Measures Group. This measures group provides eligible professionals opportunity to report assessments prior to a total knee surgery such as shared decision-making reviewing conservative therapy prior to invasive surgery, risk assessment, prophylactic antibiotic prior to tourniquet inflation, and identification of prosthesis implant within medical chart. This measures group allows Orthopedic Surgeons and other eligible professionals within this scope of practice a measures group to report.	AAHKS/ AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institutions computer systems **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows specialty Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of Computed Tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows speciality Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows speciality Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows speciality Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows speciality Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows speciality Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) who Die while in Hospital:** Percent of patients undergoing endovascular repair of small or moderate abdominal aortic aneurysms (AAA) who die while in the hospital **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure would be reported by Vascular Surgical eligible professionals. Currently, PQRS has 5 specific measures that are applicable to this scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record or #131: Pain Assessment and Follow-Up. This measure would produce data that evaluates procedural death and sequela events such as bleeding and could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure represents an outcome measure for this specific specialty.	SVS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Rate of postoperative stroke or death in Asymptomatic Patients undergoing Carotid Endarterectomy (CEA):** Percent of asymptomatic patients undergoing CEA who experience stroke or death following surgery while in the hospital **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure would be reported by Vascular Surgical eligible professionals. Currently, PQRS has 5 specific measures that are applicable to this scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record or #131: Pain Assessment and Follow-Up. This measure would produce data that evaluates procedural death and sequela events such as stroke and could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure represents an outcome measure for this specific specialty.	SVS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Rate of postoperative stroke or death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS):** Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure would be reported by Vascular Surgical eligible professionals. Currently, PQRS has 5 specific measures that are applicable to this scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record or #131: Pain Assessment and Follow-Up. This measure would produce data that evaluates procedural death and sequela events such as stroke. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure represents an outcome measure for this specific specialty.	SVS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Rate of Major Complications (Discharged to Home by Post- Operative Day #2) Carotid Artery Stenting (CAS) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post- operative day #2 **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure would be reported by Vascular Surgical eligible professionals. Currently, PQRS has 5 specific measures that are applicable to this scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record or #131: Pain Assessment and Follow-Up. This measure would produce data that evaluates procedural death and sequela events such as stroke. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure represents an outcome measure for this specific specialty.	SVS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Vascular Composite:** Optimal Vascular Care: Patients ages 18 to 75 with ischemic vascular disease (IVD) who meet all of the numerator targets of this composite measure: LDL less than 100, Blood Pressure less than 140/90, Tobacco-Free Status, and Daily Aspirin Use (unless contraindicated) **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This composite measure encompasses measurements that address risk factors for this specific patient population. This composite measure would be able to be reported by a variety of eligible professionals ranging from Family Practice to Vascular and potentially Cardiologist.	MNCM		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate:** Physician-specific risk-standardized rates of procedural complications following the implantation of an ICD **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). Electrophysiologists and eligible professionals within this scope of practice would report this measure. Currently, PQRS does not contain any measures that are specific to this scope of practice. It may be possible for these eligible professionals to report on general measures such as #130: Documentation of Current Medications in the Medical Record. CMS recognizes that PQRS contains measures that are clinically heart related, but concedes that these measures may be more relevant to General Cardiology rather than Electrophysiology. This measure would produce data that evaluates procedural death and sequela events such as lead dislodgement. This data could allow eligible professionals reporting to "benchmark" patient health post procedure. This measure represents an outcome based measure.	HRS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0209/N/A		Person and Caregiver-Centered Experience and Outcomes	**Pain Brought under Control within 48 Hours:** Number of patients who report being uncomfortable because of pain at the initial assessment (after admission to hospice services) who report pain was brought to a comfortable level within 48 hours **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure concept would be new for PQRS. There are no measures currently within the program that address care for patients that are being managed by palliative care or eligible professionals that would provide these services to patients. Pain management for patients receiving palliative care would add beneficial data to a medical concept that currently has no measurement available within this program.	NHPCO		X				
N/A/N/A		Effective Clinical Care	**Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis Access is a Catheter at the Time Maintenance Hemodialysis is Initiated:** Percentage of patients aged 18 years and older with a diagnosis of ESRD who initiate maintenance hemodialysis during the measurement period, whose mode of vascular access is via a catheter at the time maintenance hemodialysis is initiated **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure expands upon the care that is represented in adult kidney disease patient population. It allows eligible professionals providing care for these patients a greater variety of measures to report. PQRS currently has 5 adult kidney disease and 2 pediatric kidney disease individual measures for reporting. PQRS also currently has an Adult Kidney Disease Measures Group available to report.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Adult Kidney Disease: Catheter Use for Greater than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure expands upon the care that is represented in adult kidney disease patient population. It allows eligible professionals providing care for these patients a greater variety of measures to report. PQRS currently has 5 adult kidney disease and 2 pediatric kidney disease individual measures for reporting. PQRS also currently has an Adult Kidney Disease Measures Group available to report.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Appropriate Use):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 7 days of diagnosis **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a new medical concept within PQRS. The measure is reportable by Ear, Nose and Throat (ENT) and other eligible professionals within this specific scope of practice. ENT eligible professionals have a limited number of measures in the program within their scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures would also be reportable by Family Physicians, Internal Medicine and other related eligible professionals within those scopes of practice.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin Prescribed for Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients, aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, without clavulante, as a first line antibiotic at the time of diagnosis **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). These measures represent a new medical concept within PQRS. The measure is reportable by ENT and other eligible professionals within this specific scope of practice. ENT eligible professionals have a limited number of measures within their scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures would also be reportable by Family Physicians, Internal Medicine and other related eligible professionals within those scopes of practice.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). These measures represent a new medical concept within PQRS. The measure is reportable by ENT and other eligible professionals within this specific scope of practice. ENT eligible professionals have a limited number of measures within their scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures would also be reportable by Family Physicians, Internal Medicine and other related eligible professionals within those scopes of practice.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Efficiency and Cost Reduction	**Adult Sinusitis: More than 1 Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered at the time of diagnosis or received within a 90 day period after date of diagnosis **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). These measures represent a new medical concept within PQRS. The measure is reportable by ENT and other eligible professionals within this specific scope of practice. ENT eligible professionals have a limited number of measures within their scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures would also be reportable by Family Physicians, Internal Medicine and other related eligible professionals within those scopes of practice.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at >=37 and < 39 weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at =37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a new medical concept within PQRS. These individual measures are reportable by Obstetrics/Gynecologist and other eligible professionals within this specific scope of practice. They currently have a limited number of measures, including urinary incontinence, within their scope of practice. This measure would allow this specialty type of eligible professional the opportunity to report upon a specific patient sample directly related to mother/baby. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures could also possibly be reportable by Family Physicians and other related eligible professionals in a rural setting where this is seen more often. This measure represents an outcome measure.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Communication and Care Coordination	**Maternity Care: Post-Partum Follow-Up and Communication and Care Coordination:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for post- partum care within 8 weeks of giving birth who received a breast feeding evaluation and education, post- partum depression screening, post-partum glucose screening for gestational diabetes patients, and family and contraceptive planning **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a new medical concept within PQRS. These individual measures are reportable by Obstetrics/Gynecologist and other eligible professionals within this specific scope of practice. They currently have a limited number of measures, including urinary incontinence, within their scope of practice. This measure would allow this specialty type of eligible professionals the opportunity to report upon a specific patient sample directly related to mother/baby. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures could also possibly be reportable by Family Physicians and other related eligible professionals in a rural setting where this is seen more often. This measure represents an outcome measure.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Atopic Dermatitis: Overuse: Role of Antihistamine:** Percentage of patients aged 25 years or younger seen at one or more visits within a 12-month period with a diagnosis of atopic dermatitis, who did not have a diagnosis of allergic rhinitis or urticaria, who were prescribed oral nonsedating antihistamines **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). Atopic dermatitis is a new medical concept for reporting within PQRS. This would provide Dermatology and other related eligible professionals with an additional measure to report within PQRS. Dermatologists could also report upon general measures such as measure #130: Documentation of Current Medications in the Medical Record.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Tuberculosis Prevention for Psoriasis and Psoriatic Arthritis Patients on a Biological Immune Response Modifier:** This measure evaluates whether providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). Psoriasis is a new medical concept for reporting within PQRS. This measure would provide Dermatology and other related eligible professionals an additional measure to report within PQRS. This measure could also be reported by other professionals that treat joint care such as Family Practice and Rheumatologists. Other than the Family Practice, the other specialists listed above are limited in the currently PQRS measures. They could report general measures such as measure #130: Documentation of Current Medications in the Medical Record.	AAD		X					
N/A/N/A		Effective Clinical Care	**Neurosurgery: Initial Visit:** The percentage of patients aged 18 through 80 years with a diagnosis of a neurosurgical procedure or pathology who had function assessed during the initial visit to the clinician for the episode of the condition **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure would be most applicable to Neurologists and Neurosurgeons and other eligible professionals within this scope of practice. There are currently no measures in the PQRS program that are reportable for this scope of practice. This measure may represent a broad patient sample.	AANS/CNS		X					

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon:** Percentage of patients who underwent a non-emergency major surgery who had their risks of postoperative complications assessed by their surgical team prior to surgery using a data-based, patient-specific risk calculator and who received personal discussion of those risks. A higher value for this measure corresponds to higher quality **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure would be broadly applicable to a variety of surgical eligible professionals and could potentially allow reporting in surgical settings not currently available within PQRS. PQRS currently includes Perioperative surgical measures and a Perioperative Measures Group, but the procedures included in those denominators are limited to certain types of procedures or determination of pre-procedure indications such as prophylactic antibiotics. Clinically, not all surgeries are indicated for prophylactic antibiotics. This measure would potentially not have any clinical limitations.	ACS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Iatrogenic Injury to Adjacent Organ/Structure:** Percentage of patients age 65 and older who had an iatrogenic injury documented in the operative note, postoperative note, or progress note. Iatrogenic injury is an unplanned laceration, puncture, transection or cautery injury to an adjacent structure (e.g., sphincters, vasculature, nerve, other) that occurs during the index procedure, whether recognized at the time of surgery or post-operatively. Synonyms for the injury could include: hole, wound, perforation, tear, injury, laceration, cautery injury, damage, disruption, or defect **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). Addition of a General Surgery Measures Group including procedures such as ventral hernia, appendectomy, AV fistula, cholecystectomy, thyroidectomy, mastectomy, lymphadenectomy, sentinel lymph node biopsy (SLNB), or lumpectomy/breast biopsy would allow surgeons another opportunity to report via measures group reporting. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. This measure set would produce data that specifically evaluate procedural endpoints such as iatrogenic injury to adjacent organ, unplanned reoperation within 30 days, unplanned readmission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the General Surgery Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients age 65 and older who had any unplanned return to the operating room for a surgical procedure, for any reason, within 30 days of the principal operative procedure. The return to the OR may occur at any hospital or surgical facility (i.e. your hospital or at an outside hospital). Note: This definition is not meant to capture patients who go back to the operating room within 30 days for a follow-up procedure based on the pathology results from the principal operative procedure or concurrent procedure. Examples: Exclude breast biopsies which return for re-excisions; insertion of port-a-cath for chemotherapy **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). Addition of a General Surgery Measures Group including procedures such as ventral hernia, appendectomy, AV fistula, cholecystectomy, thyroidectomy, mastectomy, lymphadenectomy, sentinel lymph node biopsy (SLNB), or lumpectomy/breast biopsy. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluates procedural endpoints such as iatrogenic injury to adjacent organ, unplanned reoperation within 30 days, unplanned readmission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the General Surgery Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients age 65 and older who had a readmission (to the same or another hospital) for any reason, within 30 days of the principal procedure. The readmission has to be classified as an "inpatient" stay by the readmitting hospital, or reported by the patient/family as such **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). Addition of a General Surgery Measures Group including procedures such as ventral hernia, appendectomy, AV fistula, cholecystectomy, thyroidectomy, mastectomy, lymphadenectomy, sentinel lymph node biopsy (SLNB), or lumpectomy/breast biopsy. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluates procedural endpoints such as iatrogenic injury to adjacent organ, unplanned reoperation within 30 days, unplanned readmission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the General Surgery Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Surgical Site Infection (SSI):** Percentage of patients age 65 and older who had a surgical site infection **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). Addition of a General Surgery Measures Group including procedures such as ventral hernia, appendectomy, AV fistula, cholecystectomy, thyroidectomy, mastectomy, lymphadenectomy, sentinel lymph node biopsy (SLNB), or lumpectomy/breast biopsy. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluates procedural endpoints such as iatrogenic injury to adjacent organ, unplanned reoperation within 30 days, unplanned readmission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the General Surgery Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Iatrogenic Injury to Adjacent Organ/Structure:** Percentage of patients age 65 and older who had an iatrogenic injury documented in the operative note, postoperative note, or progress note. Iatrogenic injury is an unplanned laceration, puncture, transection or cautery injury to an adjacent structure (e.g., sphincters, vasculature, nerve, other) that occurs during the index procedure, whether recognized at the time of surgery or post-operatively. Synonyms for the injury could include: hole, wound, perforation, tear, injury, laceration, cautery injury, damage, disruption, or defect **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure contained within the Gastrointestinal (GI) Measures Group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, unplanned reoperation within 30 days, unplanned hospital admission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the Gastrointestinal (GI) Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Anastomotic Leak Intervention:** Percentage of patients age 65 and older who had an intervention (via return to operating room, interventional radiology, or interventional gastroenterology) for presence of leak of endoluminal contents (such as air, fluid, GI contents, or contrast material) through an anastomosis. The presence of an infection/abscess thought to be related to an anastomosis, even if the leak cannot be definitively identified as visualized during an operation, or by contrast extravasation would also be considered an anastomotic leak **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure contained within the Gastrointestinal (GI) Measures Group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, unplanned reoperation within 30 days, unplanned hospital admission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the Gastrointestinal (GI) Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients age 65 and older who had any unplanned return to the operating room for a surgical procedure, for any reason, within 30 days of the principal operative procedure. The return to the OR may occur at any hospital or surgical facility (i.e. your hospital or at an outside hospital). Note: This definition is not meant to capture patients who go back to the operating room within 30 days for a follow-up procedure based on the pathology results from the principal operative procedure or concurrent procedure. Examples: Exclude breast biopsies which return for re-excisions; insertion of port-a-cath for chemotherapy **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure contained within the Gastrointestinal (GI) Measures Group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, unplanned reoperation within 30 days, unplanned hospital admission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the Gastrointestinal (GI) Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients age 65 and older who had a readmission (to the same or another hospital) for any reason, within 30 days of the principal procedure. The readmission has to be classified as an "inpatient" stay by the readmitting hospital, or reported by the patient/family as such **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure contained within the Gastrointestinal (GI) Measures Group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, unplanned reoperation within 30 days, unplanned hospital admission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the Gastrointestinal (GI) Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Surgical Site Infection (SSI):** Percentage of patients age 65 and older who had a surgical site infection **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure contained within the Gastrointestinal (GI) Measures Group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, unplanned reoperation within 30 days, unplanned hospital admission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the Gastrointestinal (GI) Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0147/N/A		Patient Safety	**PN-6: Initial Antibiotic Selection for CAP in Immunocompetent** **Patient:** Immunocompetent patients with Community-Acquired Pneumonia who receive an initial antibiotic regimen during the first 24 hours that is consistent with current guidelines **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure addresses a performance gap for eligible professionals providing care to patients admitted within a hospital setting. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	CMS		X				IQR
0372/N/A		Patient Safety	**VTE-2: Intensive Care Unit Venous Thromboembolism Prophylaxis:** This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer). **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure set addresses a performance gap for eligible professionals providing care to patients admitted within a hospital setting. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	The Joint Commission		X				IQR

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**VTE-4: Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol:** This measure assesses the number of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol. **Rationale:** We are proposing this measure based on our exception authority under 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). CMS believes this measure set addresses a performance gap for eligible professionals providing care to patients admitted within a hospital setting. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	The Joint Commission		X				IQR
0495/N/A		Communication and Care Coordination	**ED-1a: Median Time from ED Arrival to ED Departure for Admitted ED Patients - Overall Rate:** Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure addresses a performance gap for eligible professionals providing care to patients assessed in the emergency department (ED). This measure would provide statistical data representing individual eligible professionals providing and coordinating medical care for patients seeking medical attention from the emergency department. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	CMS		X				IQR

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0495/N/A		Communication and Care Coordination	**ED-1d: Median Time from ED Arrival to ED Departure for Admitted Patients - Psychiatric/Mental Health Patients:** Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure addresses a performance gap for eligible professionals providing care to patients assessed in the emergency department (ED). This measure would provide statistical data representing individual eligible professionals providing and coordinating medical care for patients seeking medical attention from the emergency department. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	CMS		X				IQR

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
1659/N/A		Community/ Population Health	**IMM-1c: Pneumococcal Immunization (PPV23) – High Risk Populations (Age 5 through 64 years):** This prevention measure addresses acute care hospitalized inpatients 65 years of age and older (IMM-1b) AND inpatients aged between 5 and 64 years (IMM-1c) who are considered high risk and were screened for receipt of pneumococcal vaccine and were vaccinated prior to discharge if indicated. The numerator captures two activities; screening and the intervention of vaccine administration when indicated. As a result, patients who had documented contraindications to pneumococcal vaccine, patients who were offered and declined pneumococcal vaccine and patients who received pneumococcal vaccine anytime in the past are captured as numerator events. **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure addresses a performance gap for eligible professionals providing care to patients admitted within a hospital setting. The measure represented would provide statistical data representing population and community health for patients within a hospital setting. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	CMS		X				IQR

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0166/N/A		Communication and Care Coordination	**HCAHPS: Hospital Consumer Assessment of Healthcare Providers and Systems Survey:** 27-items survey instrument with 7 domain-level composites including: communication with doctors, communication with nurses, responsiveness of hospital staff, pain control, communication about medicines, cleanliness and quiet of the hospital environment, and discharge information **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure addresses a performance gap for eligible professionals providing care to patients admitted within a hospital setting. This measure would provide statistical data representing person and caregiver-centered experience and outcomes for patients that have experienced care within a hospital setting. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	AHRQ		X				IQR

¥ Titles and descriptions in this table are aligned with proposed 2014 Health Information Technology for Economic and Clinical Health (HITECH) measure titles, and may differ from existing measures in other programs. When reporting data on these measures, please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

In Table 30, we specify the measures we are proposing to remove from reporting under the PQRS. Please note that the rationale we have for each measure we are proposing to remove is specified after the measure title and description.

TABLE 30: Measures Proposed for Removal from the Existing Physician Quality Reporting System Measure Set Beginning in 2014

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0061/3	Effective Clinical Care	**Diabetes Mellitus: High Blood Pressure Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg) **Rationale:** Eliminating duplicative measures within PQRS.	NCQA	X	X	X		X	MU1
N/A/86	Effective Clinical Care	**Hepatitis C: Antiviral Treatment Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12-month reporting period **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI	X	X			X	
N/A/89	Effective Clinical Care	**Hepatitis C: Counseling Regarding Risk of Alcohol Consumption:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12-months **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI	X	X			X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/90	Effective Clinical Care	**Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy:** Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI	X	X			X	
N/A/161	Effective Clinical Care	**HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy:** Percentage of patients with a diagnosis of HIV/AIDS aged 13 years and older: who have a history of a nadir CD4+ cell count below 350/mm^3 or who have a history of an AIDS-defining condition, regardless of CD4+ cell count; or who are pregnant, regardless of CD4+ cell count or age, who were prescribed potent antiretroviral therapy **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI/ NCQA		X			X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/162	Effective Clinical Care	**HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who are receiving potent antiretroviral therapy, who have a viral load below limits of quantification after at least 6 months of potent antiretroviral therapy or patients whose viral load is not below limits of quantification after at least 6 months of potent antiretroviral therapy and have documentation of a plan of care **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI/ NCQA		X			X	
AQA adopted/173	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use – Screening:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, that does not have this measure available for reporting in 2014.	AMA-PCPI	X	X	X		X	
N/A/184	Community/ Population Health	**Hepatitis C: Hepatitis B Vaccination in Patients with HCV:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI	X	X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/188	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear:** Percentage of patients aged birth and older referred to a physician (preferably a physician with training in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with a congenital or traumatic deformity of the ear (internal or external) **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AQC	X	X				
N/A/200	Effective Clinical Care	**Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation:** Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI/ ACCF/AHA			X			MU1
0073/201	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Blood Pressure Management:** Percentage of patients aged 18 to 75 years with Ischemic Vascular Disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg) **Rationale:** Eliminating duplicative measures within PQRS.	NCQA	X	X	X		X	MU1

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0410/208	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for syphilis at least once within 12 months **Rationale:** Measure owner combined NQF 0410 with NQF 0409.	AMA-PCPI/ NCQA		X			X	
0445/209	Effective Clinical Care	**Functional Communication Measure - Spoken Language Comprehension:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language Comprehension Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				
0449/210	Effective Clinical Care	**Functional Communication Measure – Attention:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Attention Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0448/211	Effective Clinical Care	**Functional Communication Measure – Memory:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Memory Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				
0447/212	Effective Clinical Care	**Functional Communication Measure - Motor Speech:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Motor Speech Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				
0446/213	Effective Clinical Care	**Functional Communication Measure – Reading:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Reading Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0444/214	Effective Clinical Care	**Functional Communication Measure - Spoken Language Expression:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language Expression Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				
0442/215	Effective Clinical Care	**Functional Communication Measure – Writing:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Writing Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				
0443/216	Effective Clinical Care	**Functional Communication Measure – Swallowing:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Swallowing Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0013/237	Effective Clinical Care	**Hypertension (HTN): Blood Pressure Measurement:** Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN with blood pressure (BP) recorded **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, which does not have this measure available for reporting in 2014.	AMA-PCPI			X			
N/A/244	Effective Clinical Care	**Hypertension: Blood Pressure Management:** Percentage of patients aged 18 years and older with a diagnosis of hypertension seen within a 12 month period with a blood pressure < 140/90 mmHg OR patients with a blood pressure ≥ 140/90 mmHg and prescribed two or more anti-hypertensive medications during the most recent office visit **Rationale:** Measure deletion due to duplicative measures within PQRS.	AMA-PCPI/ ACCF/AHA		X				
0503/252	Effective Clinical Care	**Anticoagulation for Acute Pulmonary Embolus Patients:** Anticoagulation ordered for patients who have been discharged from the emergency department (ED) with a diagnosis of acute pulmonary embolus **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ACEP	X	X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/256	Communication and Care Coordination	**Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR):** Percentage of patients 18 years of age or older undergoing endovascular abdominal aortic aneurysm repair (EVAR) who have at least one follow-up imaging study after 3 months and within 15 months of EVAR placement that documents aneurysm sac diameter and endoleak status **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	SVS		X				
0012/306	Community/Population Health	**Prenatal Care: Screening for Human Immunodeficiency Virus (HIV):** Percentage of patients, regardless of age, who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal visit **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, which does not have this measure available for reporting in 2014.	AMA-PCPI			X			MU1
0014/307	Patient Safety	**Prenatal Care: Anti-D Immune Globulin:** Percentage of D (Rh) negative, unsensitized patients, regardless of age, who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, which does not have this measure available for reporting in 2014.	AMA-PCPI			X			MU1

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0027/308	Community/Population Health	**Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies:** Percentage of patients aged 18 years and older who were current smokers or tobacco users, who were seen by a practitioner during the measurement year and who received advice to quit smoking or tobacco use or whose practitioner recommended or discussed smoking or tobacco use cessation medications, methods or strategies **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, which does not have this measure available for reporting in 2014.	NCQA			X			MU1
0575/313	Effective Clinical Care	**Diabetes Mellitus: Hemoglobin A1c Control (< 8%):** The percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 or type 2) who had HbA1c < 8% **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, which does not have this measure available for reporting in 2014.	NCQA			X			

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0493/321	Communication and Care Coordination	**Participation by a Hospital, Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality:** Participation in a systematic qualified clinical database registry involves: a. Physician or other clinician submits standardized data elements to registry. b. Data elements are applicable to consensus endorsed quality measures. c. Registry measures shall include at least two (2) representative NQF consensus endorsed measures for registry's clinical topic(s) and report on all patients eligible for the selected measures. d. Registry provides calculated measures results, benchmarking, and quality improvement information to individual physicians and clinicians. e. Registry must receive data from more than 5 separate practices and may not be located (warehoused) at an individual group's practice. Participation in a national or state-wide registry is encouraged for this measure. f. Registry may provide feedback directly to the provider's local registry if one exists. **Rationale:** Due to the proposed inclusion of Qualified Clinical Data Registries, we believe this measure is redundant. Therefore, CMS is proposing to remove this measure.	OFMQ	X	X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Communication and Care Coordination	**Total Knee Replacement: Coordination of Post Discharge Care:** Percentage of patients undergoing total knee replacement who received written instructions for post discharge care including all the following: post discharge physical therapy, home health care, post discharge deep vein thrombosis (DVT) prophylaxis and follow-up physician visits **Rationale:** Measure Owner decision to remove this measure from Total Knee Replacement and replace with the measure: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy	AAHKS/ AMA-PCPI					X	
N/A/N/A	Person and Caregiver-Centered Experience and Outcomes	**Chronic Wound Care: Patient Education Regarding Long-Term Compression Therapy:** Percentage of patients aged 18 years and older with a diagnosis of venous ulcer who received education regarding the need for long term compression therapy including interval replacement of compression stockings within the 12 month reporting period **Rationale:** This measure concept is routinely met in a clinical setting. CMS believes it would not indicate a true quality outcome.	AMA-PCPI	X	X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Osteoporosis: Status of Participation in Weight-Bearing Exercise and Weight-bearing Exercise Advice:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose status regarding participation in weight-bearing exercise was documented and for those not participating regularly who received advice within 12 months to participate in weight-bearing exercise **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program	ABIM					X	
N/A/N/A	Effective Clinical Care	**Osteoporosis: Current Level of Alcohol Use and Advice on Potentially Hazardous Drinking Prevention:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose current level of alcohol use was documented and for those engaging in potentially hazardous drinking who received counseling within 12 months **Rationale:** Propose to delete this measures group due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Patient Safety	**Osteoporosis: Screen for Falls Risk Evaluation and Complete Falls Risk Assessment and Plan of Care:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a screen for falls risk evaluation within the past 12 months and for those reported as having a history of two or more falls, or fall-related injury who had a complete risk assessment for falls and a falls plan of care within the past 12 months **Rationale:** Propose to delete this measures group due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	
N/A/N/A	Effective Clinical Care	**Osteoporosis: Dual-Emission X-ray Absorptiometry (DXA) Scan:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a DXA scan and result documented **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Osteoporosis: Calcium Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had calcium intake assessment and counseling at least once within 12 months **Rationale:** Propose to delete this measures group due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	
N/A/N/A	Effective Clinical Care	**Osteoporosis: Vitamin D Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had vitamin D intake assessment and counseling at least once within 12 months **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	
N/A/N/A	Effective Clinical Care	**Osteoporosis: Pharmacologic Therapy:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who were prescribed pharmacologic therapy approved by the Food and Drug Administration **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Blood Pressure at Goal:** Percentage of patients in the sample whose most recent blood pressure reading was at goal **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Low Density Lipids (LDL) Cholesterol at Goal:** Percentage of patients in the sample whose LDL cholesterol is considered to be at goal, based upon their coronary heart disease (CHD) risk factors **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Timing of Lipid Testing Complies with Guidelines:** Percentage of patients in the sample whose timing of lipid testing complies with guidelines (lipid testing performed in the preceding 12-month period (with a three-month grace period) for patients with known coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus); or in the preceding 24-month period (with a three-month grace period) for patients with ≥ 2 risk factors for CHD (smoking, hypertension, low high density lipid (HDL), men ≥ 45 years, women ≥ 55 years, family history of premature CHD; HDL ≥ 60 mg/dL acts as a negative risk factor); or in the preceding 60-month period (with a three-month grace period) for patients with ≤ 1 risk factor for CHD) **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Diabetes Documentation or Screen Test:** Percentage of patients in the sample who had a screening test for type 2 diabetes or had a diagnosis of diabetes **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Counseling for Diet and Physical Activity:** Percentage of patients who received dietary and physical activity counseling **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program	ABIM					X	
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Correct Determination of Ten-Year Risk for Coronary Death or Myocardial Infarction (MI):** Number of patients in the sample whose ten-year risk of coronary death or MI is correctly assessed and documented **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Appropriate Use of Aspirin or Other Antiplatelet/Anticoagulant Therapy:** Percentage of patients in the sample who are: 1) taking aspirin or other anticoagulant/antiplatelet therapy, or 2) under age 30, or 3) age 30 or older and who are documented to be at low risk. Low-risk patients include those who are documented with no prior coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus) and whose ten-year risk of developing CHD is < 10% **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program	ABIM					X	
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Smoking Status and Cessation Support:** Percentage of patients in the sample whose current smoking status is documented in the chart, and if they were smokers, were documented to have received smoking cessation counseling during the reporting period. **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program	ABIM					X	

¥ Titles and descriptions in this table are aligned with the 2014 Physician Quality Reporting System Claims and Qualified Registry measure titles and descriptions, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

b. Proposed PQRS Measures Groups

Section 414.90(b) defines a measures group as ''a subset of four or more Physician Quality Reporting System measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.'' As we discussed in section IV.I.4. above, we propose to increase the number of measures reported by individual eligible professionals via claims and registry from 3 to 9. Since we are proposing to increase the number of individual measures to be reported via claims and registry, we believe it is also appropriate to increase the number of measures that would be reported in a measures group. Specifically, we propose to modify the minimum amount of measures that may be included in a PQRS measures group from four to six. Therefore, we are proposing to modify the definition of a measures group at § 414.90(b) to indicate that a measures group would consist of at least six measures. Consequently, we are proposing to add additional measures to measures groups that previously contained less than six measures. We believe that, although it is appropriate to increase the number of measures in a measures group, we do not believe it would be appropriate to increase the minimum number of reportable measures in a measures group to 9, such as we are proposing for individual eligible professionals who report individual quality measures via claims and registry. Unlike reporting individual measures, where an eligible professional would be able to report on any 9 measures of his/her choosing, an eligible professional is required to report on ALL the measures contained in a measures group. We believe increasing the number of minimum measures in a measures group to six is reasonable, as it would only require the eligible professional to report on an additional two measures.

Tables 31 through 53 specify our proposed measures groups in light of our proposal to increase the minimum number of measures in a measures group in previously established measures groups, so that each measures group contains at least 6 measures (77 FR 69272).

In addition to the measures groups that we finalized for 2013 and beyond, we are proposing the following three additional measures groups, which are identified in Tables 54 through 56:

- *Optimizing Patient Exposure to Ionizing Radiation:* This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This would be a measures group that specialty Radiologists and other eligible professionals within this scope of practice could report.

- *General Surgery:* Addition of a General Surgery Measures Group including procedures such as ventral hernia, appendectomy, AV fistula, cholecystectomy, thyroidectomy, mastectomy, lymphadenectomy, sentinel lymph node biopsy (SLNB), or lumpectomy/breast biopsy would allow surgeons another opportunity to report via measures group reporting.

- *Gastrointestinal Surgery:* This measures group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. However, these measures address a gap in that it would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, and unplanned reoperation.

Please note that, since we are proposing to eliminate the option to report measures groups via claims, all measures groups proposed for 2014 and beyond would be reportable through registry-based reporting only.

¥ Titles and descriptions in these tables are aligned with the 2014 Physician Quality Reporting System Claims and Registry measure titles and descriptions, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

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TABLE 31: Proposed Diabetes Mellitus Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0059/ 1	**Diabetes Mellitus: Hemoglobin A1c Poor Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%	NCQA
0064/ 2	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA
0055/ 117	**Diabetes Mellitus: Dilated Eye Exam:** Percentage of patients 18-75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period	NCQA
0062/ 119	**Diabetes Mellitus: Urine Protein Screening:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period	NCQA
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0056/ 163	**Diabetes Mellitus: Foot Exam:** The percentage of patients aged 18 through 75 years with diabetes who had a foot examination	NCQA

TABLE 32: Proposed Chronic Kidney Disease (CKD) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0041/ 110	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI
1668/ 121	**Adult Kidney Disease: Laboratory Testing (Lipid Profile):** Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period	AMA-PCPI

AQA adopted /122	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and proteinuria with a blood pressure < 130/80 mmHg OR ≥ 130/80 mmHg with a documented plan of care	AMA-PCPI
1666/123	**Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA) - Hemoglobin Level > 12.0 g/dL:** Percentage of calendar months within a 12-month period during which a Hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced chronic kidney disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving erythropoiesis-stimulating agent (ESA) therapy AND have a hemoglobin level > 12.0 g/dL	AMA-PCPI
0419/130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0028/226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

TABLE 33: Proposed Preventive Care Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0046/39	**Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who have a central dual-energy X- ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months	AMA-PCPI/ NCQA
0098/48	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months	AMA-PCPI/ NCQA
0041/110	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI
0043/111	**Preventive Care and Screening: Pneumococcal Vaccination for Patients 65 Years and Older:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	NCQA

0031/ 112	**Preventive Care and Screening: Breast Cancer Screening:** Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer within 24 months	NCQA
0034/ 113	**Preventive Care and Screening: Colorectal Cancer Screening:** Percentage of patients aged 50 through 75 years who received the appropriate colorectal cancer screening	NCQA
0421/ 128	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**. **Normal Parameters:** Age 65 years and older BMI ≥ 23and < 30; Age 18 – 64 years BMI > 18.5 and < 25	CMS
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

TABLE 34: Proposed Coronary Artery Bypass Graft (CABG) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0134/ 43	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG: Surgery** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft	STS
0236/ 44	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision	CMS/ QIP
0129/ 164	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours	STS
0130/ 165	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection (involving muscle, bone, and/or mediastinum requiring operative intervention)	STS
0131/ 166	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a **postoperative** stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours	STS

0114/167	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis	STS
0115/168	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason	STS
0116/169	**Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on antiplatelet medication	STS
0117/170	**Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on beta-blockers	STS
0118/171	**Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on a statin or other lipid-lowering regimen	STS

TABLE 35: Proposed Rheumatoid Arthritis (RA) Measures Group for 2014 and Beyond

NQF/PQRS	Measure Title and Description	Measure Developer
0054/108	**Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy:** Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a DMARD	NCQA
AQA adopted /176	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of RA who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD)	AMA-PCPI
AQA adopted /177	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease activity within 12 months	AMA-PCPI
AQA adopted /178	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months	AMA-PCPI
AQA adopted /179	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease prognosis at least once within 12 months	AMA-PCPI
AQA adopted /180	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of RA who have been assessed for glucocorticoid use and, for those on prolonged doses of	AMA-PCPI

NQF/ PQRS	Measure Title and Description	Measure Developer
	prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months	

TABLE 36: Proposed Perioperative Care Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0270/ 20	**Perioperative Care: Timing of Prophylactic Parenteral Antibiotic – Ordering Physician:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic parenteral antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required)	AMA-PCPI/ NCQA
0268/ 21	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	AMA-PCPI/ NCQA
0271/ 22	**Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures):** Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time	AMA-PCPI/ NCQA
0239/ 23	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	AMA-PCPI/ NCQA
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS

0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ N/A	**Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon:** Percentage of patients who underwent a non-emergency major surgery who had their risks of postoperative complications assessed by their surgical team prior to surgery using a data-based, patient-specific risk calculator and who received personal discussion of those risks. A higher value for this measure corresponds to higher quality	ACS

TABLE37: Proposed Back Pain Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0420/ 131	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment through discussion with the patient including the use of a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	CMS
0322/ 148	**Back Pain: Initial Visit:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain	NCQA
0319/ 149/	**Back Pain: Physical Exam:** Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received a physical examination at the initial visit to the clinician for the episode of back pain	NCQA
0314/ 150	**Back Pain: Advice for Normal Activities:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice for normal activities at the initial visit to the clinician for the episode of back pain	NCQA
0313/ 151	**Back Pain: Advice Against Bed Rest:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting four days or longer at the initial visit to the clinician for the episode of back pain	NCQA

TABLE 38: Proposed Hepatitis C Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0395/ 84	**Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed within 6 months prior to initiation of antiviral treatment	AMA-PCPI
0396/ 85	**Hepatitis C: HCV Genotype Testing Prior to Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom HCV genotype testing was performed prior to initiation of antiviral treatment	AMA-PCPI
0398/ 87	**Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing at Week 12 of Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment	AMA-PCPI
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0399/ 183	**Hepatitis C: Hepatitis A Vaccination in Patients with Hepatitis C Virus (HCV):** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A	AMA-PCPI
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

TABLE 39: Proposed Heart Failure (HF) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0081/ 5	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at **each** hospital discharge	AMA-PCPI/ ACCF/ AHA
0083/ 8	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at **each** hospital discharge	AMA-PCPI/ ACCF/ AHA
0421/ 128	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**. **Normal Parameters:** Age 65 years and older BMI ≥ 23and < 30; Age 18 – 64 years BMI > 18.5 and < 25	CMS
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0079/ 198	**Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment:** Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative results of a recent or prior [any time in the past] LVEF assessment is documented within a 12 month period	AMA-PCPI/ ACCF/ AHA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

TABLE 40: Proposed Coronary Artery Disease (CAD) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0067/ 6	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel	AMA-PCPI/ ACCF/ AHA
0421/ 128	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**. **Normal Parameters:** Age 65 years and older BMI ≥ 23and < 30; Age 18 – 64 years BMI > 18.5 and < 25	CMS
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0074/ 197	**Coronary Artery Disease (CAD): Lipid Control:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C < 100 mg/dL, including at a minimum the prescription of a statin	AMA-PCPI/ ACCF/ AHA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ 242	**Coronary Artery Disease (CAD): Symptom Management:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period with an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with appropriate management of anginal symptoms within a 12 month period	AMA-PCPI/ ACCF/ AHA

TABLE 41: Proposed Ischemic Vascular Disease (IVD) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0421/ 128	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**.	CMS
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0068/ 204	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with documented use of aspirin or another antithrombotic	NCQA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
0018/ 236	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg)	NCQA
0075/ 241	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)	NCQA

TABLE 42: Proposed HIV/AIDS Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0404/ 159	**HIV/AIDS: CD4+ Cell Count or CD4+ Percentage:** Percentage of patients aged 6 months and older with a diagnosis of HIV/AIDS for whom a CD4+ cell count or CD4+ cell percentage was performed at least once every 6 months	AMA-PCPI/ NCQA
0405/ 160	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 years and older with a diagnosis of HIV/AIDS and CD4+ cell count < 200 cells/mm^3 who were prescribed PCP prophylaxis within 3 months of low CD4+ cell count	AMA-PCPI/ NCQA
0409/ 205	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection and who were screened for syphilis at least once within 12 months	AMA-PCPI/ NCQA
2082/ N/A	**HIV Viral Load Suppression:** Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year	HRSA
2083/ N/A	**Prescription of HIV Antiretroviral Therapy:** Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year	HRSA
2079/ N/A	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits	HRSA
2080/ N/A	**Gap in HIV medical visits:** Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 month of the measurement year	HRSA

TABLE 43: Proposed Asthma Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0047/ 53	**Asthma: Pharmacologic Therapy for Persistent Asthma - Ambulatory Care Setting:** Percentage of patients aged 5 through 64 years with a diagnosis of persistent asthma who were prescribed long-term control medication. Three rates are reported for this measure: 1. Patients prescribed inhaled corticosteroids (ICS) as their long term control medication. 2. Patients prescribed other alternative long term control medications (non-ICS). 3. Total patients prescribed long-term control medication	AMA-PCPI/ NCQA
0001/ 64	**Asthma: Assessment of Asthma Control – Ambulatory Care Setting:** Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were evaluated at least once during the measurement period for asthma control (comprising asthma impairment and asthma risk)	AMA-PCPI/ NCQA
0041/ 110	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
N/A/ 231	**Asthma: Tobacco Use: Screening - Ambulatory Care Setting:** Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were queried about tobacco use and exposure to second hand smoke within their home environment at least once during the one-year measurement period	AMA-PCPI/ NCQA
N/A/ 232	**Asthma: Tobacco Use: Intervention - Ambulatory Care Setting:** Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were identified as tobacco users (patients who currently use tobacco AND patients who do not currently use tobacco, but are exposed to second hand smoke in their home environment) who received tobacco cessation intervention at least once during the one-year measurement period	AMA-PCPI/ NCQA

TABLE 44: Proposed Chronic Obstructive Pulmonary Disease (COPD) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0091/ 51	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented	AMA-PCPI
0102/ 52	**Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 60% and have symptoms who were prescribed an inhaled bronchodilator	AMA-PCPI
0041/ 110	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0043/ 111	**Preventive Care and Screening: Pneumococcal Vaccination for Patients 65 Years and Older:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	NCQA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

TABLE 45: Proposed Inflammatory Bowel Disease (IBD) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ 269	**Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All Documented:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have documented the disease type, anatomic location and activity, at least once during the reporting period	AGA

N/A/ 270	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days that have been prescribed corticosteroid sparing therapy in the last reporting year	AGA
N/A/ 271	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have received dose of corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days and were assessed for risk of bone loss once per the reporting year	AGA
N/A/ 272	**Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom influenza immunization was recommended, administered or previously received during the reporting year	AGA
N/A/ 273	**Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease that had pneumococcal vaccination administered or previously received	AGA
N/A/ 274	**Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA
N/A/ 275	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA

TABLE 46: Proposed Sleep Apnea Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0421/ 128	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**. **Normal Parameters:** Age 65 years and older BMI $\geq$ 23and $<$ 30; Age 18 – 64 years BMI $>$ 18.5 and $<$ 25	CMS

0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ 276	**Sleep Apnea: Assessment of Sleep Symptoms:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness	AMA-PCPI/ NCQA
N/A/ 277	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis	AMA-PCPI/ NCQA
N/A/ 278	**Sleep Apnea: Positive Airway Pressure Therapy Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy	AMA-PCPI/ NCQA
N/A/ 279	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured	AMA-PCPI/ NCQA

TABLE 47: Proposed Dementia Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A / 280	**Dementia: Staging of Dementia:** Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period	AMA-PCPI
N/A / 281	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period	AMA-PCPI
N/A / 282	**Dementia: Functional Status Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of patient's functional status is performed and the results reviewed at least once within a 12 month period	AMA-PCPI

N/A / 283	**Dementia: Neuropsychiatric Symptom Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of patient's neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period	AMA-PCPI
N/A / 284	**Dementia: Management of Neuropsychiatric Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period	AMA-PCPI
N/A / 285	**Dementia: Screening for Depressive Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period	AMA-PCPI
N/A / 286	**Dementia: Counseling Regarding Safety Concerns:** Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period	AMA-PCPI
N/A / 287	**Dementia: Counseling Regarding Risks of Driving:** Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and alternatives to driving at least once within a 12 month period	AMA-PCPI
N/A / 288	**Dementia: Caregiver Education and Support:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period	AMA-PCPI

TABLE 48: Proposed Parkinson's Disease Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A / 289	**Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review:** All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (e.g., medications that can produce Parkinson-like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually	AAN
N/A / 290	**Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually	AAN
N/A / 291	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually	AAN

N/A / 292	**Parkinson's Disease: Querying about Sleep Disturbances:** All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about sleep disturbances at least annually	AAN
N/A / 293	**Parkinson's Disease: Rehabilitative Therapy Options:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually	AAN
N/A / 294	**Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually	AAN

TABLE 49: Proposed Hypertension Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ 295	**Hypertension: Appropriate Use of Aspirin or Other Antithrombotic Therapy:** Percentage of patients aged 30 through 90 years old with a diagnosis of hypertension and are eligible for aspirin or other antithrombotic therapy who were prescribed aspirin or other antithrombotic therapy	ABIM
N/A/ 296	**Hypertension: Complete Lipid Profile:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within **60 months**	ABIM
N/A/ 297	**Hypertension: Urine Protein Test:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who either have chronic kidney disease diagnosis documented or had a urine protein test done within **36 months**	ABIM
N/A/ 298	**Hypertension: Annual Serum Creatinine Test:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within **12 months**	ABIM
N/A/ 299	**Hypertension: Diabetes Mellitus Screening Test:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a diabetes screening test within **36 months**	ABIM
N/A/ 300	**Hypertension: Blood Pressure Control:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had most recent blood pressure level under control (< 140/90 mmHG)	ABIM
N/A/ 301	**Hypertension: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had most recent LDL cholesterol level under control (at goal)	ABIM

N/A/ 302	**Hypertension: Dietary and Physical Activity Modifications Appropriately Prescribed:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received dietary and physical activity counseling at least once within **12 months**	ABIM

TABLE 50: Proposed Cardiovascular Prevention Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0064/ 2	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA
0068/ 204	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with documented use of aspirin or another antithrombotic	NCQA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
0018/ 236	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg)	NCQA
0075/ 241	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)	NCQA
N/A/ 317	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure (BP) AND a recommended follow-up plan is documented based on the current blood pressure reading as indicated	CMS/ QIP

TABLE 51: Proposed Cataracts Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL	CMS

	prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	
0565/ 191	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery	AMA-PCPI/ NCQA
0564/ 192	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence	AMA-PCPI/ NCQA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ 303	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey	AAO
N/A/ 304	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey	AAO
N/A/ N/A	**Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon:** Percentage of patients who underwent a non-emergency major surgery who had their risks of postoperative complications assessed by their surgical team prior to surgery using a data-based, patient-specific risk calculator and who received personal discussion of those risks. A higher value for this measure corresponds to higher quality	ACS

TABLE 52: Proposed Oncology Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0387/ 71	**Breast Cancer: Hormonal Therapy for Stage IC -IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer:** Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period	AMA-PCPI/ ASCO/ NCCN
0385/ 72	**Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients:** Percentage of patients aged 18 through 80 years with AJCC Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period	AMA-PCPI/ ASCO/ NCCN
0041/ 110	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list **must** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration	CMS/ QIP
0384/ 143	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patients, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	AMA-PCPI
0383/ 144	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain	AMA-PCPI
0386/ 194	**Oncology: Cancer Stage Documented:** Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline American Joint Committee on Cancer (AJCC) cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period	AMA-PCPI/ ASCO
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

TABLE 53: Proposed Total Knee Replacement Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list **must** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration	CMS/ QIP
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A / N/A	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. NSAIDs, analgesics, exercise, injections) prior to the procedure	AAHKS /AMA-PCPI
N/A / N/A	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including history of deep vein thrombosis (DVT), pulmonary embolism (PE), myocardial infarction (MI), arrhythmia and stroke	AAHKS /AMA-PCPI
N/A / N/A	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	AAHKS /AMA-PCPI
N/A / N/A	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of prosthetic implant and the size of prosthetic implant	AAHKS /AMA-PCPI

TABLE 54: Proposed Optimizing Patient Exposure to Ionizing Radiation Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title	Measure Developer
N/A/ N/A	**Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institutions computer systems	AMA-PCPI
N/A/ N/A	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of Computed Tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study	AMA-PCPI
N/A/ N/A	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements	AMA-PCPI
N/A/ N/A	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study	AMA-PCPI
N/A/ N/A	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed	AMA-PCPI

N/A/ N/A	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (eg, follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors	AMA-PCPI

TABLE 55: Proposed General Surgery Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list **must** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration	CMS/ QIP
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ N/A	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Iatrogenic Injury to Adjacent Organ/Structure:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had an iatrogenic injury documented in the operative note, postoperative note, or progress note. Iatrogenic injury is an unplanned laceration, puncture, transection or cautery injury to an adjacent structure (e.g., sphincters, vasculature, nerve, other) that occurs during the index procedure, whether recognized at the time of surgery or post-operatively. Synonyms for the injury could include: hole, wound, perforation, tear, injury, laceration, cautery injury, damage, disruption, or defect	ACS

N/A/ N/A	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Unplanned Reoperation within the 30 Day Postoperative Period:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had any unplanned return to the operating room for a surgical procedure, for any reason, within 30 days of the principal operative procedure. The return to the OR may occur at any hospital or surgical facility (i.e. your hospital or at an outside hospital). Note: This definition is not meant to capture patients who go back to the operating room within 30 days for a follow-up procedure based on the pathology results from the principal operative procedure or concurrent procedure. Examples: Exclude breast biopsies which return for re-excisions; insertion of port-a-cath for chemotherapy	ACS
N/A/ N/A	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Unplanned Hospital Readmission within 30 Days of Principal Procedure:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who a readmission (to the same or another hospital) for any reason, within 30 days of the principal procedure. The readmission has to be classified as an "inpatient" stay by the readmitting hospital, or reported by the patient/family as such	ACS
N/A/ N/A	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Surgical Site Infection (SSI):** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had a surgical site infection	ACS
N/A/ N/A	**Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon:** Percentage of patients who underwent a non-emergency major surgery who had their risks of postoperative complications assessed by their surgical team prior to surgery using a data-based, patient-specific risk calculator and who received personal discussion of those risks. A higher value for this measure corresponds to higher quality	ACS

TABLE 56: Proposed Gastrointestinal Surgery Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list **must** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration	CMS/ QIP
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ N/A	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Iatrogenic Injury to Adjacent Organ/Structure:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had an iatrogenic injury documented in the operative note, postoperative note, or progress note. Iatrogenic injury is an unplanned laceration, puncture, transection or cautery injury to an adjacent structure (e.g., sphincters, vasculature, nerve, other) that occurs during the index procedure, whether recognized at the time of surgery or post-operatively. Synonyms for the injury could include: hole, wound, perforation, tear, injury, laceration, cautery injury, damage, disruption, or defect	ACS
N/A/ N/A	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Anastomotic Leak Intervention:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had an intervention (via return to operating room, interventional radiology, or interventional gastroenterology) for presence of leak of endoluminal contents (such as air, fluid, GI contents, or contrast material) through an anastomosis. The presence of an infection/abscess thought to be related to an anastomosis, even if the leak cannot be definitively identified as visualized during an operation, or by contrast extravasation would also be considered an anastomotic leak	ACS

N/A/ N/A	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Unplanned Reoperation within the 30 Day Postoperative Period:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had any unplanned return to the operating room for a surgical procedure, for any reason, within 30 days of the principal operative procedure. The return to the OR may occur at any hospital or surgical facility (i.e. your hospital or at an outside hospital). Note: This definition is not meant to capture patients who go back to the operating room within 30 days for a follow-up procedure based on the pathology results from the principal operative procedure or concurrent procedure. Examples: Exclude breast biopsies which return for re-excisions; insertion of port-a-cath for chemotherapy	ACS
N/A/ N/A	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Unplanned Hospital Readmission within 30 Days of Principal Procedure:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who a readmission (to the same or another hospital) for any reason, within 30 days of the principal procedure. The readmission has to be classified as an "inpatient" stay by the readmitting hospital, or reported by the patient/family as such	ACS
N/A/ N/A	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Surgical Site Infection (SSI):** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had a surgical site infection	ACS
N/A/ N/A	**Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon:** Percentage of patients who underwent a non-emergency major surgery who had their risks of postoperative complications assessed by their surgical team prior to surgery using a data-based, patient-specific risk calculator and who received personal discussion of those risks. A higher value for this measure corresponds to higher quality	ACS

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We seek public comment on these proposals.

c. Proposed Reporting Mechanism Changes to PQRS Individual Measures for 2014 and Beyond

In addition to the measures and measures groups we are proposing to include or remove from the existing PQRS measure set, we propose to modify how existing PQRS measures can be reported. Specifically, we propose that the following measures would no longer be reportable through the claims-based reporting mechanism:

- PQRS #9 (NQF# 0105): Major Depressive Disorder (MDD): Antidepressant Medication during Acute Phase for Patients with MDD: Percentage of patients aged 18 years and older diagnosed with new episode of MDD and documented as treated with antidepressant medication during the entire 84-day (12-week) acute treatment phase. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient number of measures for these eligible professionals to report via claims.
- PQRS #64 (NQF# 0001): Asthma: Assessment of Asthma Control—Ambulatory Care Setting: Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated at least once for asthma control (comprising asthma impairment and asthma risk). *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This measure is contained within the asthma measures group.
- PQRS #53: Asthma: Pharmacologic Therapy for Persistent Asthma—Ambulatory Care Setting. *Rationale:* Changing PQRS measure #64 to a

registry only measure would affect this measure. There would be no way to use the MAV with this measure because it is part of the MAV cluster associated with PQRS #64.

- PQRS #65 (NQF# 0069): Appropriate Treatment for Children with Upper Respiratory Infection (URI): Percentage of children aged 3 months through 18 years with a diagnosis of URI who were not prescribed or dispensed an antibiotic prescription on or within 3 days of the initial date of service. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #66 (NQF# 0002): Appropriate Testing for Children with Pharyngitis: Percentage of children aged 2 through 18 years with a diagnosis of pharyngitis, who were prescribed an antibiotic and who received a group A streptococcus (strep) test for the episode. A higher rate represents better performance (that is, appropriate testing). *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #87 (NQF# 0398): Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #89 (NQF# 0401): Hepatitis C: Counseling Regarding Risk of Alcohol Consumption: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12-months. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #90 (NQF# 0394): Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy: Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic Hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims
- PQRS #116 (NQF# 0058): Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use: Percentage of adults aged 18 through 64 years with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or within 3 days of the initial date of service. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #126: DM: Diabetic Foot and Ankle Care, Peripheral Neuropathy-Neurological Evaluation. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #127 (NQF# 0416): Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention—Evaluation of Footwear: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #176 (AQA Adopted): Rheumatoid Arthritis (RA): Tuberculosis Screening: Percentage of patients aged 18 years and older with a diagnosis of RA who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD). *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #177 (AQA Adopted): Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity: Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease activity within 12 months. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #178 (AQA Adopted): Rheumatoid Arthritis (RA): Functional Status Assessment: Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #179 (AQA Adopted): Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis: Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease prognosis at least once within 12 months. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #148 (NQF# 0322): Back Pain: Initial Visit: Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain. *Rationale:* We believe this measure (which is only reportable when reporting the entire Back Pain measures group) is more appropriately reported via registry.
- PQRS #149 (NQF# 0319): Back Pain: Physical Exam: Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received a physical examination at the initial visit to the clinician for the episode of back pain. *Rationale:* We believe this measure (which is only reportable when reporting the entire Back Pain measures group) is more appropriately reported via registry.

• PQRS #150 (NQF# 0314): Back Pain: Advice for Normal Activities: Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice for normal activities at the initial visit to the clinician for the episode of back pain. *Rationale:* We believe this measure (which is only reportable when reporting the entire Back Pain measures group) is more appropriately reported via registry.

• PQRS #151 (NQF# 0313): Back Pain: Advice Against Bed Rest: Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting four days or longer at the initial visit to the clinician for the episode of back pain. *Rationale:* We believe this measure (which is only reportable when reporting the entire Back Pain measures group) is more appropriately reported via registry.

d. The Clinician Group (CG) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

Because we believe these patient surveys are important tools for assessing beneficiary experience of care and outcomes, under our authority under section 1848(m)(3)(C) of the Act to select the measures for which a group practice must report, we previously proposed a new satisfactory reporting criterion in this section to provide group practices comprised of 25 or more eligible professionals the option to complete the CG CAHPS survey for purposes of satisfying the 2014 PQRS incentive and 2016 PQRS payment adjustment. Specifically, the survey measures that we propose to use for the PQRS program includes the following 12 summary survey measures:

• Getting timely care, appointments, and information;
• How well providers Communicate;
• Patient's Rating of Provider;
• Access to Specialists;
• Health Promotion & Education;
• Shared Decision Making;
• Health Status/Functional Status;
• Courteous and Helpful Office Staff;
• Care Coordination;
• Between Visit Communication;
• Helping Your to Take Medication as Directed; and
• Stewardship of Patient Resources.

The first seven measures proposed above are the same ones used in the Medicare Shared Savings Programs. As stated previously, we believe it is important to align measures across programs to the extent possible. The remaining five measures proposed above address arreas of high importance to Medicare and are areas where patient experience can inform the quality of care related to care coordination and efficiency. Please note that the group practice would bear the cost of having this survey administered. We seek public comment on these proposed measures.

11. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Participation in a Qualified Clinical Data Registry for 2014 and Beyond for Individual Eligible Professionals

For the measures for which eligible professionals participating in a qualified clinical data registry must report, section 1848(m)(3)(D) of the Act, as amended and added by section 601(b) of the American Tax Relief Act of 2012, provides that the Secretary shall treat eligible professionals as satisfactorily submitting data on quality measures if they satisfactorily participate in a qualified clinical data registry. Section 1848(m)(3)(E) of the Act, as added by section 601(b) of the American Tax Relief Act of 2012, provides some flexibility with regard to the types of measures applicable to satisfactory participation in a qualified clinical data registry, by specifying that with respect to measures used by a qualified clinical data registry, sections 1890(b)(7) and 1890A(a) of the Act shall not apply, and measures endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act may be used. We propose to provide to qualified clinical data registries flexibility with regard to choosing the quality measures data available for individual eligible professionals to choose from to report to CMS using these qualified clinical data registries. We believe it is preferable for the qualified clinical data registries with flexibility in selecting measures since we believe these clinical data registries would know best what measures should be reported to achieve the goal of improving the quality of care furnished by their eligible professionals. Although we are proposing to allow these clinical data registries to determine the quality measures from which individual eligible professionals would choose to have reported to CMS, to ensure that CMS receives the same type of data that could be uniformly analyzed by CMS and sufficient measure data, we believe it is important to set parameters on the measures to be reported on and the types of measures should be reported to CMS. Therefore, we are proposing the following requirements for the measures that must be reported to CMS by a qualified clinical data registry for the purpose of its individual eligible professionals meeting the criteria for satisfactory participation under the PQRS:

• The qualified clinical data registry must have at least 9 measures, covering at least 3 of the 6 National Quality Strategy domains, available for reporting. The 6 National Quality Strategy domains are as follows:

++ *Person and Caregiver-Centered Experience and Outcomes.* These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level as well as the population level through greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.

++ *Patient Safety.* These are measures that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.

++ Communication and *Care Coordination.* These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families in order to improve appropriate and timely patient and care team communication.

++ *Community/Population Health.* These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.

++ *Efficiency and Cost Reduction.* These are measures that reflect efforts to significantly improve outcomes and reduce errors. These measures also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.

++ *Effective Clinical Care.* These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

• The qualified clinical data registry must have at least 1 outcome measure available for reporting, which is a measure that assesses the results of health care that are experienced by patients (that is, patients' clinical events; patients' recovery and health status; patients' experiences in the health system; and efficiency/cost).

• The qualified clinical data registry may report on process measures, which are measures that focus on a process which leads to a certain outcome, meaning that a scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome.

• The outcome and process measures reported must contain denominator data. That is, the lower portion of a fraction used to calculate a rate, proportion, or ratio. The denominator must describe the population eligible (or episodes of care) to be evaluated by the measure. This should indicate age, condition, setting, and timeframe (when applicable). For example, ''Patients aged 18 through 75 years with a diagnosis of diabetes.''

• The outcome and process measures reported must contain numerator data. That is, the upper portion of a fraction used to calculate a rate, proportion, or ratio. The numerator must detail the quality clinical action expected that satisfies the condition(s) and is the focus of the measurement for each patient, procedure, or other unit of measurement established by the denominator (that is, patients who received a particular service or providers that completed a specific outcome/process).

• The qualified clinical data registry must provide denominator exceptions for the measures, where approriate. That is, those conditions that should remove a patient, procedure or unit of measurement from the denominator of the performance rate only if the numerator criteria are not met. Denominator exceptions allow for adjustment of the calculated score for those providers with higher risk populations. Denominator exceptions allow for the exercise of clinical judgment and should be specifically defined where capturing the information in a structured manner fits the clinical workflow. Generic denominator exception reasons used in measures fall into three general categories: Medical, Patient, or System reasons.

• The qualified clinical data registry must provide denominator exclusions for the measures for which it will report to CMS, where appropriate. That is, those patients with conditions who should be removed from the measure population and denominator before determining if numerator criteria are met. (For example, Patients with bilateral lower extremity amputations would be listed as a denominator exclusion for a measure requiring foot exams.)

• The qualified clinical data registry must provide to CMS descriptions for the measures for which it will report to CMS by no later than March 31, 2014. The descriptions must include: name/title of measures, NQF # (if NQF endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions and denominator exclusions of the measure.

We request comments on these proposals.

12. Proposals for PQRS Informal Review

Section 414.90(j) provides that eligible professionals and group practices may request an informal review of the determination that an eligible professional or group practice did not satisfactorily submit data on quality measures under the PQRS. Because we believe it is important to also allow eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry to be able to request an informal review of the determination that the eligible professional satisfactorily participated in a qualified clinical data registry, we are proposing to modify § 414.90(j) to allow individual eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry the opportunity to request an informal review. We are not proposing to make any changes to the informal review process itself; rather, we propose to make the existing informal review process available to individual eligible professionals with regard to a determination that the individual eligible professional did not satisfactorily participate in a qualified clinical data registry.

We seek public comment on this proposal.

13. Plan for the Future of PQRS for the 2017 PQRS Payment Adjustment and Beyond

a. Future PQRS Reporting Periods

Under § 414.90(h)(1), the reporting period for the PQRS payment adjustment, for the payment adjustment year, is the 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied. When we first proposed the reporting periods for the PQRS payment adjustment, we received many comments from stakeholders who opposed basing the PQRS payment adjustment year on a reporting period occurring two years prior to the payment adjustment year (77 FR 69176). Stakeholders requested that CMS establish reporting periods occurring closer to the year in which the payment adjustment is applied. Although we understood the commenters' concerns, we stated it was not operationally feasible to create a full calendar year reporting period for the PQRS payment adjustment any later than two years prior to the adjustment year and still avoid retroactive payments or the reprocessing of claims. Although it is still operationally infeasible to establish a 12-month reporting period occurring any later than two years prior to the adjustment year for reporting via claims, we are seeking comment about this issue again. In particular, in future years, should CMS consider establishing a reporting period that occurs closer to the adjustment year for certain PQRS reporting mechanisms, such as the registry, EHR, and GPRO web interface reporting mechanisms? Also, should the reporting periods still be structured as 12-month reporting periods occurring in a calendar year or multiple years? What length of time should be used for the reporting period? For example, should the PQRS allow for shorter, quarterly reporting periods? We would consider such comments to the extent we address or revisit the reporting period for the PQRS payment adjustment in future rulemaking.

b. Plan for the Future of the PQRS GPRO

The PQRS GPRO has undergone significant changes since it was first introduced in 2010. Given stakeholder feedback with claims that constant changes to the GPRO has caused confusion for GPRO participants, we did not propose many changes to the GPRO for the 2014 PQRS incentive or 2016 PQRS payment adjustment. However, we continue to receive stakeholder feedback urging CMS to reconsider certain policies related to the GPRO, such as:

• *The definition of a PQRS group practice that limits the practice to a single TIN.* A group practice in PQRS is currently defined at § 414.90(b) as ''a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their billing rights to the TIN.'' Therefore, for group practices, CMS uses the TIN as the billing unit. Any PQRS incentive payments earned

are paid to the TIN holder of record. Stakeholders believe that limiting the definition of a group practice to ''a single TIN'' causes operational challenges to group practices that may operate as one healthcare entity but, due to business purposes, bill Medicare using multiple TINs.

This definition has become increasingly problematic particularly as some CMS programs with quality reporting components allow group practices containing multiple TINs to participate in these programs as a single group practice. We understand this concern. Therefore, we seek comment on whether we should modify the current definition of group practice to account for multiple TINs (that is, change the identification unit(s) to recognize a group practice). In addition, if we allow groups with multiple TINs to participate in PQRS as a single group practice, we seek comment on what parameters we should put in place. For example, if we allow multiple TINs to participate in PQRS as a single group practice, should we place geographical restrictions? Should we require that groups wishing to participate as a single group practice provide care for the same beneficiaries?

• *Self-Nomination/Registration Process.* We currently require group practices to self-nominate for each program year the group practices wish to participate in PQRS using the GPRO. Stakeholders have commented that annual self-nomination is duplicative, particularly when no changes to a group practice's composition have been made. We therefore seek comment as to whether, in future years, we should move away from requiring group practices to self-nominate/register for the GPRO each year. Once a group practice is approved to participate in PQRS as a GPRO, should we automatically assume that a group practice would participate in PQRS as a GPRO for future years until the group practice indicates otherwise?

• *Satisfactory Reporting Criterion for Group Practices Using the GPRO web interface.* Currently, if the pool of assigned beneficiaries for a group practice using the GPRO web interface is less than the specified reporting threshold (i.e., 411 assigned beneficiaries for group practices comprised of 100 or more eligible professionals), then the group practice is required to report on 100 percent of assigned beneficiaries for purposes of both the PQRS incentive and payment adjustment. Conceivably, a group practice could have as few as one beneficiary assigned to the group practice and still qualify for the PQRS incentive or avoid the PQRS payment adjustment as long as the group practice successfully reports the measures included in the web interface for that one beneficiary. As data collected from the GPRO web interface starts getting used to calculate performance benchmarks for the Value-based Payment Modifier and/or Physician Compare, we question whether performance results from group practices with few assigned beneficiaries could skew the benchmark calculations. We, therefore, invite comment on whether we should establish minimum reporting thresholds for group practices using the GPRO web interface as well as seek comment on what the appropriate thresholds should be. Or, should we consider requiring group practices to be in existence prior to the start of the reporting period to use the GPRO web interface?

c. Future of Use of the Claims-Based Reporting Mechanism in PQRS

According to the 2011 PQRS and eRx Experience Report, approximately 72 percent of eligible professionals (229,282 out of 320,422 eligible professionals) participating in PQRS in 2011 did so using the claims-based reporting mechanism. The claims-based reporting mechanism is the most widely used PQRS reporting mechanism. Unfortunately, the claims-based reporting mechanism is also the reporting mechanism that allows for the most errors in reporting. Unlike the registry and EHR-based reporting mechanisms, where the quality measures data is submitted at the end of the reporting period, eligible professionals must report quality measures data at the time they submit their claims for payment for services. Therefore, registry and EHR users are at an advantage as they are able to analyze their quality data at the end of the year for any changes that may need to be made due to follow up care. In addition, it is burdensome for CMS to analyze quality measures data from the claims-based reporting mechanism because it takes several months to analyze all claims for which reporting G-codes are submitted to CMS.

For these reasons, we seek comment as to whether CMS should eliminate the claims-based reporting mechanism beginning with the reporting period (calendar year 2017) for the 2019 PQRS payment adjustment.

d. Future Submission Timelines for the Registry, EHR, GPRO Web Interface and Qualified Clinical Data Registry Reporting Mechanisms

In the CY 2013 PFS final rule, we finalized the following deadlines for submitting quality measures data via claims, registry, EHR, and the GPRO web interface:

• For an eligible professional submitting PQRS quality measures data via claims, an eligible professional is required to submit no later than the last Friday of the second month after the end of the reporting period, that is, processed by February 28, 2014 for the reporting periods that end December 31, 2013 (77 FR 69178).

• For eligible professionals and group practices submitting quality measures data via registry and EHR, the registry or EHR is required to submit quality measures data no later than the last Friday of the February following the applicable reporting period (for example, February 28, 2014 for reporting periods occurring in 2013) (77 FR 69182).

• For group practices submitting quality measures data via the GPRO web interface, we stated we would provide group practices that are selected to participate in the GPRO using GPRO web interface reporting option with access to the GPRO web interface by no later than the first quarter of the year following the end of the reporting period under which the group practice intends to report (77 FR 69187). For example, for group practices selected for the GPRO for the 2013 incentive using the GPRO web interface tool, group practices selected to participate in the GPRO would be provided with access to the GPRO web interface by no later than the first quarter of 2014 for purposes of reporting for the applicable 2013 reporting period for the incentive.

We have received feedback from eligible professionals, group practices, and vendors that the submission deadlines come too soon after the close of the reporting period. Vendors, in particular, find it difficult to meet the submission deadlines in time to submit quality measures data on behalf of all their participating eligible professionals and group practices. While it is not technically feasible to allow for submission of quality measures data reported via claims any later than the last Friday of the second month after the end of the respective reporting period, we are exploring alternative deadlines for quality measures data that is submitted via registry, EHR, the GPRO web interface, and the newly proposed qualified clinical data registry.

Specifically, we are exploring ways to collect quality measures data on a quarterly basis, rather than allowing for submission of quality measures data only once following a respective reporting period. We seek public comment on allowing for quarterly submission of quality measures data as well as other alternatives that would allow CMS with the time necessary to perform quality measures data analysis prior to the assessment of PQRS payment adjustments.

e. Integration of Clinical Quality Measures Reported Under the Hospital Inpatient Quality Reporting (IQR) Program

We received feedback that, for certain hospital-based physicians who bill Medicare Part B services and therefore are able to participate in PQRS, the measures CMS has adopted under the PQRS do not adequately capture the nature of their practice. These physicians believe that measures such as those available in the Hospital IQR Program are more relevant to the quality of care these physicians provide. Therefore, under Section I.9, we proposed to include measures available under the Hospital IQR Program that have been retooled to be reported under the PQRS during the 12-month 2014 PQRS incentive and 12-month 2016 PQRS payment adjustment reporting periods via the registry-based reporting mechanism. We seek comment on whether additional Hospital IQR measures should be retooled for use in the PQRS in the same manner. In addition, we seek comment on whether CMS should attribute the reporting periods and performance results from the hospital IQR program to individual eligible professionals or group practices who elect to have their hospital's performance scores attributed to them.

f. Feedback Reports

For eligible professionals reporting PQRS quality measures data via claims, CMS provides each eligible professional who submits a valid reporting quality data code (QDC) two feedback reports each year that provides detailed information on an eligible professional's reporting performance. These feedback reports only provide data on PQRS reporting performance. Given our efforts to align with the Value-based Payment Modifier, we are exploring ways to merge the feedback reports provided to participants in the PQRS and Value-based Payment Modifier so that an eligible professional would receive one, merged feedback report showing reporting data for the PQRS and performance data for the Value-based Payment Modifier. We seek public comment on whether feedback reports for the PQRS and Value-based Payment Modifier should be merged.

I. Electronic Health Record (EHR) Incentive Program

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified EHR technology (CEHRT). Section 1848(o)(2)(B)(iii) of the Act requires that in selecting clinical quality measures (CQMs) for eligible professionals (EPs) to report under the EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. As such, we have taken steps to establish alignments among various quality reporting and payment programs that include the submission of CQMs.

For CY 2012 and subsequent years, § 495.8(a)(2)(ii) requires an EP to successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable, in the form and manner specified by CMS or the states, as applicable. In the EHR Incentive Program Stage 2 Final Rule, we established clinical quality measure reporting options for the Medicare EHR Incentive Program for CY 2014 and subsequent years that include one individual reporting option that aligns with the PQRS's EHR reporting option (77 FR 54058) and two group reporting options that align with the PQRS GPRO and Medicare Shared Savings Program (MSSP) and Pioneer ACOs (77 FR 54076 to 54078). In this proposed rule, we are proposing two additional aligned options for EPs to report CQMs for the Medicare EHR Incentive Program for CY 2014 and subsequent years with the intention of minimizing the reporting burden on EPs.

1. Proposed Qualified Clinical Data Registry Reporting Option

Section 1848(m)(7) of the Act (''Integration of Physician Quality Reporting'') requires the Secretary to develop a plan to integrate reporting on quality measures under the PQRS with reporting requirements related to meaningful use under the EHR Incentive Program. In response to section 1848(m)(7) of the Act, the PQRS and EHR Incentive Program have, in particular, taken steps to align their respective quality measures reporting criteria. For example, in the CY 2013 PFS final rule with comment period (77 FR 69190), the PQRS adopted criteria for satisfactory reporting for the 2014 PQRS incentive that aligns with the criteria for meeting the CQM component of achieving meaningful use under the Medicare EHR Incentive Program in 2014. Specifically, under the PQRS, an individual EP will meet the criteria for satisfactory reporting for the 2014 PQRS incentive using a direct EHR or EHR data submission vendor product that is CEHRT certified to the 2014 Edition certification criteria if, during the 12-month 2014 PQRS incentive reporting period, the EP reports 9 measures covering at least 3 National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is patient data (see Table 91, 77 FR 69194 through 69195).

As further described in section G of this proposed rule, section 1848(m)(3)(D) of the Act, as amended and added by section 601(b) of the American Taxpayer Relief Act of 2012, includes a provision that authorizes an additional standard for individual eligible professionals to meet the PQRS by satisfactorily participating in a qualified clinical data registry. In section G of this proposed rule, we proposed criteria for eligible professionals to satisfactorily participate in a qualified clinical data registry for the 2014 PQRS incentive.

For purposes of meeting the CQM reporting component of meaningful use for the Medicare EHR Incentive Program in 2014 and subsequent years, we propose to allow EPs to submit CQM information using qualified clinical data registries, according to the proposed definition and requirements for qualified clinical data registries discussed in section IV.I. of this proposed rule. We are proposing this new option under the Medicare EHR Incentive Program beginning with the reporting periods in 2014 for the following reasons: (1) To minimize duplicative reporting as directed under section 1848(o)(2)(B)(iii) of the Act for EPs who seek to participate in both the Medicare EHR Incentive Program and a qualified clinical data registry under the PQRS in 2014; (2) to further integrate reporting quality reporting options under the PQRS and the EHR Incentive Program as directed under section 1848(m)(7) of the Act; and (3) because the proposed criteria for the satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive are similar to criteria we finalized for meeting the CQM component of achieving meaningful use under the

Medicare EHR Incentive Program for 2014. In the event that the criteria established for satisfactory participation in a qualified clinical data registry under PQRS in the final rule are different from the proposed criteria, we intend to adopt the criteria that are finalized for PQRS to the extent feasible for the Medicare EHR Incentive Program. In addition to the criteria that are ultimately established for PQRS, we propose the following additional criteria that an EP who seeks to report CQMs for the Medicare EHR Incentive Program using a qualified clinical data registry must satisfy: (1) The EP must use CEHRT as required under the Medicare EHR Incentive Program; (2) the CQMs reported must be included in the Stage 2 final rule (see Table 8, 77 FR 54069) and use the same electronic specifications established for the EHR Incentive Program, (3) report 9 CQMs covering at least 3 domains, (4) if an EP's CEHRT does not contain patient data for at least 9 CQMs covering at least 3 domains, then the EP must report the CQMs for which there is patient data and report the remaining CQMs as ''zero denominators'' as displayed by the EP's CEHRT, and (5) an EP must have CEHRT that is certified to all of the certification criteria required for CQMs, including certification of the qualified clinical data registry itself for the functions it will fulfill (for example, calculation, electronic submission). We note that these proposed additional criteria are already final policies for the CQM reporting options that we established for EPs in the EHR Incentive Program Stage 2 final rule. We refer readers to that final rule for further explanation of the policies related to clinical quality measure reporting under the EHR Incentive Program (77 FR 54049–54089). The electronic specifications for the clinical quality measures can be found at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*. We are proposing this qualified clinical data registry reporting option only for those EPs who are beyond their first year of demonstrating meaningful use (MU). For purposes of avoiding a payment adjustment under Medicare, EPs who are in their first year of demonstrating MU in the year immediately preceding a payment adjustment year must satisfy their CQM reporting requirements by October 1 of such preceding year (for example, by October 1, 2014 to avoid a payment adjustment in 2015). The proposed qualified clinical data registry reporting option would not enable an EP to meet the deadline to avoid a payment adjustment because these qualified clinical data registries would be submitting data on CQMs by the last day of February following the 2014 PQRS incentive reporting periods, which would occur after October 1, 2013. Therefore, EPs who are first-time meaningful EHR users must report CQMs via attestation as established in the EHR Incentive Program Stage 2 final rule (77 FR 54050). The reporting periods established in the EHR Incentive Program Stage 2 final rule would continue to apply to EPs who would choose to report CQMs under this proposed qualified clinical data registry reporting option for purposes of the Medicare EHR Incentive Program (77 FR 54049–54051). Please note that this may not satisfy requirements for other quality reporting programs that have established 12-month reporting periods, such as the PQRS.

Under section 1848(o)(2)(A)(iii) of the Act, EPs are required to use CEHRT to submit information on clinical quality measures for the EHR Incentive Program. The 2014 Edition certification criteria established by the Office of the National Coordinator for Health IT (ONC) set the requirements for certification that cover the functionality needed to ''capture and export'' (45 CFR 170.314(c)(1)), ''import and calculate'' (45 CFR 170.314(c)(2)), and for ''electronic submission'' (45 CFR 170.314(c)(3)) of each CQM that will be reported.

As EPs are required to use CEHRT under section 1848(o)(2)(A)(iii) of the Act, we propose that for the Medicare EHR Incentive Program, an EP who seeks to report using a qualified clinical data registry that meets the criteria established for PQRS must also ensure that the registry selected is certified for the functionality that it is intended to fulfill and is a certified EHR Module that is part of the EP's CEHRT. For example, if the registry would collect patient level data from EPs, calculate the CQMs, then submit to CMS the calculated results on behalf of the EP in either an aggregate level Quality Reporting Document Architecture (QRDA) Category III file or patient level QRDA–I files, then the registry would need to be certified for the CQM criteria listed at 45 CFR 170.314(c)(2) (''import and calculate'') for each CQM that will be submitted and 45 CFR 170.314(c)(3) (''electronic submission''). We note that EPs would still need to include a certified EHR Module as part of their CEHRT that is certified to the CQM criteria listed at 45 CFR 170.314(c)(1) (''capture and export'') for each of the CQMs that would be submitted to CMS for the purposes of meeting the CQM requirements of the Medicare EHR Incentive Program. If the qualified clinical data registry is performing the function of data capture for the CQMs that would be submitted to CMS, then the registry would need to be certified to the ''capture and export'' criteria listed at 45 CFR 170.314(c)(1). The certified EHR Module must be part of the EP's CEHRT.

We intend to revisit the certification criteria with ONC in the Stage 3 rulemaking for the purpose of developing a more flexible clinical data registry reporting option and certification criteria for the EHR Incentive Program when Stage 3 begins. We welcome public comment and recommendations on a more flexible clinical data registry reporting option for meeting the CQM reporting requirement for MU and on the certification criteria that ONC could incorporate for clinical data registries.

2. Proposed Group Reporting Option—Comprehensive Primary Care Initiative

The Comprehensive Primary Care (CPC) Initiative, under the authority of section 3021 of the Affordable Care Act, is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. Under this initiative, CMS will pay participating primary care practices a care management fee to support enhanced, coordinated services. Simultaneously, participating commercial, State, and other federal insurance plans are also offering an enhanced payment to primary care practices that provide high-quality primary care. There are approximately 500 CPC participants across 7 health care markets in the U.S. More details on the CPC Initiative can be found at *http://innovation.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html*.

CPC practice sites will submit a subset of the CQMs that were selected in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 (77 FR 54069–54075). In a continuing effort to align quality reporting programs and innovation initiatives, we propose to add a group reporting option for CQMs for the Medicare EHR Incentive Program beginning in CY 2014 for EPs who are part of a CPC practice site that successfully submits at least 9 electronically specified CQMs covering 3 domains. We propose that each of the EPs in the CPC practice site would satisfy the CQM reporting component of meaningful use for the relevant

reporting period if the CPC practice site successfully submits and meets the reporting requirements of the CPC Initiative. We propose that only those EPs who are beyond their first year of demonstrating meaningful use may use this proposed CPC group reporting option, for the reasons explained in the preceding section in regard to avoiding a payment adjustment under Medicare. We propose that EPs who successfully submit as part of a CPC practice site in accordance with the requirements established for the CPC Initiative and using CEHRT would satisfy their CQM reporting requirement for the Medicare EHR Incentive Program. The CPC practice sites must submit the CQM data in the form and manner required by the CPC Initiative.

If a CPC practice site fails the requirements established for the CPC Initiative, we note that the EPs who are part of the site would have the opportunity to report CQMs per the requirements established in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 (77 FR 54049). We invite public comment on these proposals.

3. Reporting of Electronically Specified Clinical Quality Measures for the Medicare EHR Incentive Program

In the EHR Incentive Program Stage 2 final rule, we finalized the CQMs from which EPs would report beginning in CY 2014 under the EHR Incentive Program (77 FR 54069, Table 8). These CQMs are electronically specified and updated routinely to account for issues such as changes in billing and diagnosis codes and changes in medical practices. The requirements specified in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 allow for the reporting of different versions of the CQMs. However, it is not technically feasible for CMS to accept data that is reported according to the specifications of the older versions of the CQMs, including versions that may be allowed for reporting under the EHR Incentive Program. We stated in the EHR Incentive Program Stage 2 final rule that, consistent with section 1848(o)(2)(B)(ii) of the Act, in the event that the Secretary does not have the capacity to receive CQM data electronically, EPs may continue to report CQM data through attestation (77 FR 54076). Therefore, we propose that EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program must use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. For example, for the reporting periods in 2014, EPs who want to report CQM data electronically for purposes of satisfying the quality measure reporting component of meaningful use would be required to use the June 2013 version of the CQMs electronic specifications (available at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*) and ensure that their CEHRT has been tested and certified to the June 2013 version of the CQMs for purposes of achieving the CQM component of meaningful use in 2014. EPs who do not wish to report CQMs electronically using the most recent version of the electronic specifications (for example, if their CEHRT has not been certified for that particular version) would be allowed to report CQM data to CMS by attestation for the Medicare EHR Incentive Program. For further explanation of reporting CQMs by attestation, we refer readers to the EHR Incentive Program Stage 1 final rule (77 FR 44430 through 44434) and the EHR Incentive Program's Registration and Attestation page (available at *https://ehrincentives.cms.gov/hitech/login.action*).

We invite public comment on these proposals. Specifically, we invite comment on whether there would be sufficient time for EHR technology developers to update their systems and timely distribute the updated CQM versions in a way that would enable EPs to report on the updated versions. Additionally, we invite comment on whether there are any data or logic dependencies in the eCQMs that EHR technology developers have experienced which, if not built in upfront and deployed before a reporting period, would result in inaccurate measures, if for example, an EHR technology was upgraded in the middle of an EP's reporting period to the newest version of the CQMs (if we finalized our proposal to only accept the lasted published specification of an CQM).

J. Medicare Shared Savings Program

Under section 1899 of the Act, CMS has established a Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in healthcare costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule implementing the Shared Savings Program appeared in the **Federal Register** on November 2, 2011 (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802)).

ACOs are required to completely and accurately report on all quality performance measures for all quality measurement reporting periods in each performance year of their agreement period. There are currently 33 quality performance measures under the Shared Savings Program. For Shared Savings Program ACOs beginning their agreement period in April or July, 2012, there will be two reporting periods in the first performance year, corresponding to calendar years 2012 and 2013. For ACOs beginning their agreement periods in 2013 or later, both the performance year and reporting period will correspond to the calendar year. Reporting on measures associated with a reporting period will generally be done in the spring of the following calendar year. For example, an ACO will submit quality measures for the 2015 reporting period in the spring of 2016.

1. Medicare Shared Savings Program and Physician Quality Reporting System Payment Adjustment

Section 1899(b)(3)(D) of the Act affords the Secretary discretion to ''* * * incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848 * * *'' and permits the Secretary to ''use alternative criteria than would otherwise apply [under section 1848 of the Act] for determining whether to make such payments.'' Under this authority, we incorporated certain Physician Quality Reporting System (PQRS) reporting requirements and incentive payments into the Shared Savings Program, including (1) The 22 GPRO quality measures identified in Table 1 of the final rule (76 FR 67889 through 67890); (2) reporting via the GPRO web interface; (3) criteria for satisfactory reporting; and (4) set January 1 through December 31 as the reporting period. The regulation governing the incorporation of PQRS incentives and reporting requirements

under the Shared Savings Program is set forth at § 425.504.

Under section 1848(a)(8) of the Act, a payment adjustment will apply under the PQRS beginning in 2015 based on quality reporting during the applicable reporting period. Eligible professionals who are not satisfactory reporters will be subject to a payment adjustment applied to the PFS amount for covered professional services furnished by the eligible professional during 2015. For eligible professionals subject to the 2015 PQRS payment adjustment, the fee schedule amount is equal to 98.5 percent (and 98 percent for 2016 and each subsequent year) of the fee schedule amount that would otherwise apply to such services. To continue to align Shared Savings Program requirements with PQRS, for the 2013 reporting period (which will be used to determine the 2015 PQRS payment adjustment to PFS amounts), in the CY 2013 PFS final rule with comment (77 FR 69372), we amended § 425.504 to include the PQRS reporting requirements necessary for eligible professionals in an ACO to avoid the 2015 PQRS payment adjustment. Specifically, we required ACOs on behalf of eligible professionals that are ACO providers/suppliers to successfully report one ACO GPRO measure in 2013 to avoid the payment adjustment in 2015. We also provided that ACO providers/suppliers that are eligible professionals may only participate under their ACO participant TIN as a group practice under the PQRS GPRO for purposes of avoiding the payment adjustment in 2015. Thus, ACO providers/suppliers who are eligible professionals may not seek to avoid the payment adjustment by reporting either as an individual under the traditional PQRS or under the traditional PQRS GPRO under their ACO participant TIN. We note, however, that eligible professionals may bill Medicare under more than one TIN (for example, eligible professionals may bill Medicare under a non-ACO participant TIN in one practice location and also bill Medicare under the TIN of an ACO participant at another practice location). As a result, ACO provider/suppliers who are eligible professionals that bill under a non-ACO participant TIN during the year could participate under the traditional PQRS as either individual EPs or a group practice for purposes of avoiding the PQRS payment adjustment for the claims billed under the non-ACO participant TIN. In fact, such EPs would have to do so to avoid the PQRS payment adjustment with respect to those claims because the regulation at § 425.504 only applies to claims submitted by ACO providers/suppliers that are eligible professionals billing under an ACO participant TIN. If eligible professionals within an ACO meet the requirements for the PQRS payment adjustment established under the Shared Savings Program, only the claims billed through the TIN of the ACO participant will avoid the payment adjustment in 2015.

For the 2014 reporting period and subsequent reporting periods (which would apply to the PQRS payment adjustment for 2016 and subsequent payment years), we propose to align with the requirements for reporting under the traditional PQRS GPRO through the CMS web interface by amending § 425.504 to require that ACOs on behalf of their ACO providers/suppliers who are eligible professionals satisfactorily report the 22 ACO GPRO measures during the 2014 and subsequent reporting periods to avoid the downward PQRS payment adjustment for 2016 and subsequent payment years. Additionally, we propose to continue the current requirement that ACO providers/suppliers who are eligible professionals may only participate under their ACO participant TIN for purposes of the payment adjustment in 2016 and subsequent years.

We believe that the proposal to modify the requirements for ACOs to satisfactorily report the 22 ACO GPRO measures to avoid the 2016 payment adjustments would not increase burden on ACOs or on ACO providers/suppliers that are eligible professionals because ACOs must already report these measures in order to satisfy the Shared Savings Program quality performance standard. Thus, this proposal would not increase the total number of measures that must be reported by the ACO and its ACO providers/suppliers that are eligible professionals. We also note that these proposals would not affect the Shared Savings Program quality performance standard reporting requirement under which ACOs are currently required to report on 33 quality performance measures, which include all 22 of the ACO GPRO quality measures.

Additionally, ACOs are required to report certain measures using the GPRO web interface tool. Specifically, § 425.504(a)(1) and (b)(1) require that ACOs submit quality measures using the GPRO web interface to qualify on behalf of their eligible professionals for the PQRS incentive or to avoid the PQRS payment adjustment. This reporting mechanism is also referenced in § 425.308(e), which provides that quality measures that ACOs report using the GPRO web interface will be reported by CMS on Physician Compare.

Under § 414.90(h)(3)(i), group practices may report data under the traditional PQRS GPRO through a CMS web interface. The Shared Savings Program regulations 425.504(a)(1) and (b)(1) and § 425.308(e) specifically reference the use of the GPRO web interface for quality reporting purposes. We propose to amend these regulations to replace references to GPRO web interface with CMS web interface. We believe this change will ensure consistency with the reporting mechanism used under 414.90(h)(3)(i) and will also allow for the flexibility to use a similar web interface in the event that operational issues are encountered with the use of the GPRO web interface. We invite public comment on this proposal.

2. Medicare Shared Savings Program-Establishing the Quality Performance Benchmark

Section 1899(b)(3)(C) of the Act directs the Secretary to ''* * * establish quality performance standards to assess the quality of care furnished by ACOs * * *'' and to ''improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care.'' In the Shared Savings Program final rule, we finalized the following requirements with regard to establishing a performance benchmark for measures: (1) During the first performance year for an ACO, the quality performance standard is set at the level of complete and accurate reporting; (2) during subsequent performance years, the quality performance standard will be phased in such that ACOs will be assessed on their performance on each measure; (3) CMS designates a performance benchmark and minimum attainment level for each measure, and establishes a point scale for the measures; and (4) contingent upon data availability, performance benchmarks are defined by CMS based on national Medicare fee-for-service rates, national Medicare Advantage (MA) quality measure rates, or a national flat percentage. In the final rule, we indicated that we would not compare an ACO's quality performance to the performance of other ACOs for purposes of determining an ACO's overall quality score. We acknowledged, however, that in future program years, we should seek to incorporate actual ACO performance on quality measures into the quality benchmarks after seeking industry input through rulemaking.

a. Data Sources Used To Establish Performance Benchmarks

The regulation governing the data that CMS will use to establish the performance benchmarks for quality performance measures under the Shared Savings Program is set forth at § 425.502(b)(2). This provision states that CMS will define the performance benchmarks based on national Medicare fee-for-service rates, national MA quality measure rates, or a national flat percentage. In the Shared Savings Program final rule, we responded to comments suggesting that quality performance benchmarks be set based on actual historical data submitted by ACOs. We stated that although we agreed that we should seek to incorporate actual ACO performance on quality scores into the quality benchmark, we would do so only in future rulemaking so that we could seek industry input. In addition, we noted that we expected to update the quality benchmarks over time, consistent with section 1899(b)(3)(C) of the Act, which requires CMS to seek to improve the quality of care furnished by ACOs participating in the Shared Savings Program over time.

Consistent with our stated intention to incorporate actual ACO experience into quality measure benchmarks, for the 2014 reporting period, we propose to amend § 425.502(b)(2) to permit CMS to use all available and applicable national Medicare Advantage and Medicare FFS performance data to set the quality performance benchmarks. Specifically, in addition to using available national Medicare FFS rates, which include data reported through PQRS, and national MA quality measure rates, we propose to use data submitted by Shared Savings Program and Pioneer ACOs in 2013 for the 2012 reporting period to set the performance benchmarks for the 2014 reporting period. We propose to publish the quality benchmarks based upon these data prior to the beginning of the 2014 reporting period through subregulatory guidance. As stated in the Shared Savings Program final rule, we will establish benchmarks using the most currently available data source and the most recent available year of benchmark data prior to the start of the reporting period. In other words, data collected in 2014 from the 2013 reporting period would be used in conjunction with other available data to set benchmarks for the 2015 reporting period, and so on. We propose to retain the option of using flat percentages when data are unavailable, inadequate or unreliable to set quality performance benchmarks. Further, we clarify our intent to combine data derived from national Medicare Advantage and national Medicare FFS to set performance benchmarks when the measure specifications used under Medicare Advantage and FFS Medicare are the same. We propose to revise § 425.502(b)(2)(i) to reflect this clarification. We seek comment on these proposals, and whether there are other data sources that should be considered in setting performance benchmarks.

b. Ensuring Meaningful Differences in Performance Rates

Data collected by CMS from the GPRO and Physician Group Practice Demonstration participants in 2012 coupled with previous CMS experience indicates that using actual data to calculate quality performance may result in some measures' performance rates being tightly clustered. In this case, quality scores for the measure may not reflect clinically meaningful differences between the performance rates achieved by reporters of quality. For example, for some measures, the distribution of performance rates may have a spread of less than 2.0 percentage points between the 30th and 90th percentiles. In such an instance, even though there is little distinction in actual performance rates, a slight difference in performance on the measure may result in a significant difference in the number of quality points obtained for the Shared Savings Program. For example, two separate ACOs at the 50th percentile and the 90th percentile may have only a few tenths of a percentage point difference in their actual performance, but under the Shared Savings Program scoring methodology, the difference between their quality scores for that measure would be more noteworthy (1.4 points versus 2.0 points).

We continue to believe it is desirable to use performance rates for measures based on actual data because doing this creates benchmarks that are simple to understand and apply, even if the rates are clustered, as the data reflect achievable performance on quality measures. However, allowing clustered performance rates for a measure may result in payment differences that are not be associated with clinically meaningful differences in patient care, as noted in the example above.

Keeping these issues in mind, we propose to develop a methodology to spread clustered performance on measures. The first step in developing that methodology is to identify when performance on a measure is clustered. Clustering could be defined as less than a certain spread between performance rates in an identified range, for example, less than 6.0 percentage points between the performance rates associated with the 30th and 90th percentiles, or less than 10.0 percentage points between the minimum and maximum values achieved by previous reporters of the quality measure. Alternatively, clustering could be defined as a spread of performance rates of less than x percentage points between any two deciles, for example, less than a 1.0 percentage point difference between the 60th and 70th decile.

Once a clustered measure has been identified, the next step is to apply a methodology to spread or separate the performance rates within the measure. It is important to establish a meaningful performance rate, or starting point, around which to differentiate or spread the performance. For example, selecting a certain percentile or median value may represent one option for establishing a reasonable starting point. Once the starting point is set, then we could implement a series of fixed percentage point intervals around the starting point in both a positive and negative direction to increase the spread, for example, applying a fixed 1.0 percentage point interval between scored deciles. For example, if the starting point is the 60th percentile, and the performance rates at the 60th and 70th percentiles were observed to be 77.15 and 77.65 respectively, there would be only a 0.5 spread between the deciles. In contrast, applying a fixed 1.0 percentage point interval to increase spread would result in a 1.0 difference between these rates, and the new performance rates would be 77.15 and 78.15 at the 60th and 70th percentiles, respectively. In the alternative, we could take the spread calculated from a subset (for example, ACO performance only) of the underlying performance data if we believe that data reported by ACOs show a different variability than other data sources. For example, the spread between the measure's percentiles could be based on historical ACO distribution only, not the historical distribution of Medicare Advantage and/or national fee-for-service, PQRS, and ACO data. The historical ACO distribution could then be applied to the Medicare Advantage and/or national fee-for-service, PQRS, and ACO percentile distribution to establish the measure's percentiles.

We believe that a clinically meaningful assessment of ACO quality is important. We also are interested in providing a pathway for ACOs new to quality reporting to achieve the quality reporting standard, and an incentive for

experienced ACOs to continue improving and performing at high levels. We are therefore proposing to use a standardized method for calculating benchmark rates when a measure's performance rates are tightly clustered. We propose that the application of a methodology to reduce measure clustering would only apply to quality measures whose performance rates are calculated as percentiles, that is, the methodology would not apply to measures whose performance rates are calculated as ratios, for example, measures such as the two ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measure. We believe that measures whose performance rates are calculated as ratios already demonstrate a high degree of clinically meaningful differences because they are risk adjusted to reflect the health status of the patient population being measured.

We propose to define a tightly clustered measure, including clinical process and outcome measures reported through the GPRO web interface and CAHPS measures, as one that demonstrates less than a 6.0 percentage point spread in performance rates between the 30th and 90th percentiles. We believe using the 30th and 90th percentiles as the lower and upper bounds is reasonable because these bounds have been given some significance in earlier rulemaking; specifically, the Shared Savings Program rule sets the ACO's minimum attainment level at the 30th percentile, below which the ACO achieves no points, and the ACO achieves full points for quality reporting at or above the 90th percentile. Further, we propose to establish the starting point at the 60th percentile, the midpoint between the 30th and 90th percentiles, and then apply a positive 1.0 fixed percentage point interval for each decile above the 60th percentile and a negative 1.0 fixed percentage point interval for each decile below the 60th percentile.

We recognize that spreading tightly clustered performance measures would decrease the lower bound necessary to meet the minimum attainment level for the measure, giving ACOs new to quality reporting a greater opportunity to meet the quality performance standard. At the same time, spreading tightly clustered performance rates would increase the upper bound necessary for achieving the maximum available quality points for the measure, giving already experienced ACOs an incentive to continue improving quality. Applying a 1.0 fixed percentage point interval achieves the goal of creating meaningful differences in performance. Further, we believe that applying a 1.0 fixed percentage point interval represents a tempered and reasonable interval that does not spread performance rates to levels that are too easy to achieve on the lower bound or too difficult to achieve on the upper bound.

For example, Table 57 demonstrates the original spread of a quality measure, based on all available data, which is compressed from a range of 75.83 at the 30th percentile to 79.23 at the 90th percentile, that is, a spread of less than 6.0 percentage points. When the proposed methodology is applied, the 60th percentile (or 77.15 percent), serving as the starting point, remains unchanged. The spread increases 6.0 percentage points from 74.15 at the 30th percentile to 80.15 at the 90th percentile. As demonstrated and explained above, this methodology improves the distinction in performance between the minimum attainment level (30th percentile) and the maximum attainment level (90th percentile).

TABLE 57—PROPOSED METHODOLOGY TO REDUCE CLUSTERED PERFORMANCE RATES

Percentile	30th	40th	50th	60th	70th	80th	90th
Original performance rates using all available data	75.83	76.21	76.76	77.15	77.65	78.21	79.23
Performance rates using methodology to reduce clustering	74.15	75.15	76.15	77.15	78.15	79.15	80.15

*Example is for illustration purposes only and is not based on actual data.

We propose to amend § 425.502(b) to reflect this methodology to reduce clustering. We are seeking comment on these proposals. Specifically, we are seeking comment on whether or not a methodology should be applied to spread out clustered performance on measures. We are also seeking comment on the proposal to define clustered performance on a measure as one in which the spread of performance rates between the 30th and 90th percentiles is less than 6.0 percentage points, or whether other values should be used to define clustered measure performance, for example, when the minimum and maximum reported values are spread by less than 10.0 percentage points. We are seeking comment on whether there are alternative methodologies that should be considered to spread out clustered performance on measures. In addition, we are seeking comment on whether measures that are calculated as ratios should be excluded from this methodology. We are also seeking comment on whether all available relevant data should be considered when developing the spread between measures, or whether only the relevant performance data from a subset of reporters, such as ACO-reported data, as discussed above, should be used to determine the appropriate spread between deciles.

c. Scoring CAHPS Measures Within the Patient Experience of Care Domain

The preamble to the Shared Savings Program final rule (76 FR 67895–67900) outlines the total potential points available per domain as demonstrated in Table 58. As indicated in Table 58, under the final rule the Patient/Caregiver Experience Domain is weighted equally with other three quality domains at 25 percent and consists of 2 measures: a composite of six Clinician and Group (CG) CAHPS summary survey measures (1) Getting Timely Care, Appointments and Information, (2) How Well Your Doctors Communicate, (3) Patient's Rating of Doctor, (4) Access to Specialists, (5) Health Promotion and Education, (6) Shared Decision Making) and a Health Status/Functional Status measure. The six measures included in the composite will transition to pay-for-performance starting in the second year of an ACO's agreement period. In contrast, the Health Status/Functional Status measure will remain pay-for-reporting throughout the ACO's entire agreement period.

TABLE 58—TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Total individual measures (table F1)	Total measures for scoring purposes	Total potential points per domain	Domain weight (percent)
Patient/Caregiver Experience	7	1 measure, with 6 survey module measures combined, plus 1 individual measure.	4	25
Care Coordination/ Patient Safety	6	6 measures, plus the EHR measure double-weighted (4 points) ..	14	25
Preventative Health	8	8 measures	16	25
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure.	14	25
Total	33	23	48	100

*From Table 4 in the Shared Savings Program Final Rule (76 FR 67899).

The result of this point system is that performance on the six patient experience measures is worth only 12.5 percent of an ACO's total performance score because the other 12.5 percent of the Patient/Caregiver Experience domain is the Health Status/Functional Status measure, which is a pay-for-reporting measure for all program years. However, we believe that each of these seven measures is equally important within the Patient/Caregiver Experience domain, and that scoring within the domain should better reflect performance on these measures, thereby placing a greater emphasis on the voice of the patient through patient-reported outcomes and experiences. We believe that increasing the weight of the 6 measures that will become pay-for-performance in the second year of the agreement period will incentivize ACOs to improve their performance on these measures. A policy to place a greater emphasis on patient-reported outcomes and experiences is consistent with our goal to improve the quality of care furnished by ACOs over time.

Therefore, we are proposing to modify the point scoring for the Patient/Caregiver Experience domain as demonstrated in Table 59. As modified, each of the 7 survey module measures within the domain would be assigned a maximum value of 2 points. The Patient/Caregiver Experience domain would then be worth a total of 14 points, rather than 4 points. The end result would be that each of the 7 measure modules in the domain would have equal weight. We note that this change would not affect the weighting of the domain itself in relationship to the other three domains; it would remain 25 percent of the ACO's total quality performance score.

TABLE 59—MODIFIED TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Total individual measures (table F1)	Total measures for scoring purposes	Total potential points per domain	Domain weight (percent)
Patient/Caregiver Experience	7	7 individual survey module measures	14	25
Care Coordination/Patient Safety	6	6 measures, plus the EHR measure double-weighted (4 points) ..	14	25
Preventative Health	8	8 measures	16	25
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure.	14	25
Total	33	28	58	100

We believe that giving equal weight to each of the Patient/Caregiver Experience measures modules is appropriate because it places greater emphasis on patient-reported experiences, promotes clinically meaningful differences in ACO performance within the domain, and is consistent with the statutory mandate to improve quality of care furnished by ACOs over time. The proposed change would also bring the total points for the domain in line with the points available in other domains.

We seek comment on our proposal to modify the point scoring within the Patient/Caregiver Experience domain.

K. Value-Based Payment Modifier and Physician Feedback Program

1. Overview

Section 1848(p) of the Act requires that we establish a value-based payment modifier and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015 and to all physicians and groups of physicians by January 1, 2017. On or after January 1, 2017, section 1848(p)(7) of the Act provides the Secretary discretion to apply the value-based payment modifier to eligible professionals as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the value-based payment modifier to be budget neutral.

In this proposed rule, we continue to phase in implementation of the value-based payment modifier by applying it to small groups of physicians and by increasing the amount of payment at risk. We also propose to refine the methodologies used in our approach to calculating the value-based payment modifier in order to better identify both high and low performers for upward and downward payment adjustments.

2. Governing Principles for Physician Value-Based Payment Modifier Implementation

In the CY 2013 PFS final rule with comment period (77 FR 69306), we

stated that the value-based payment modifier has the potential to help transform Medicare from a passive payer to an active purchaser of higher quality, more efficient and more effective healthcare by providing upward payment adjustments under the PFS to high performing physicians (and groups of physicians) and downward adjustments for low performing physicians (and groups of physicians). We also noted that Medicare is implementing value-based payment adjustments for other types of services, including inpatient hospital services. Further, in implementing value-based purchasing initiatives generally, we seek to recognize and reward high quality care and quality improvements, and to promote more efficient and effective care through the use of evidence-based measures, the reduction in administrative burden and duplication, and less fragmented care.

In the CY 2013 PFS final rule with comment period, we established that the following specific principles should govern the implementation of the value-based payment modifier (77 FR 69307).

- *A focus on measurement and alignment.* Measures for the value-based payment modifier should consistently reflect differences in performance among physicians and physician groups, reflect the diversity of services furnished, and be consistent with the National Quality Strategy and other CMS quality initiatives, including the PQRS, the Medicare Shared Savings Program, and the Medicare EHR Incentive Program.
- *A focus on physician choice.* Physicians should be able to choose the level (individual or group) at which their quality performance will be assessed, reflecting physicians' choice over their practice configurations. The choice of level should align with the requirements of other physician quality reporting programs.
- *A focus on shared accountability.* The value-based payment modifier can facilitate shared accountability by assessing performance at the group practice level and by focusing on the total costs of care, not just the costs of care furnished by an individual physician.
- *A focus on actionable information.* The Physician Feedback reports should provide meaningful and actionable information to help groups of physicians and physicians identify clinical areas where they are doing well, as well as areas in which performance could be improved by providing groups of physicians with feedback reports on the quality and cost of care they furnish to their patients.
- *A focus on a gradual implementation.* The value-based payment modifier should focus initially on identifying high and low performing groups of physicians. Moreover, groups of physicians should be able to elect how the value-based payment modifier would apply to their payment under the PFS starting in CY 2015. As we gain more experience with physician measurement tools and methodologies, we can broaden the scope of measures assessed, refine physician peer groups, create finer payment distinctions, and provide greater payment incentives for high performance.

3. Overview of Existing Policies for the Physician Value-Based Payment Modifier

In the CY 2013 PFS final rule with comment period, we finalized policies to phase-in the value-based payment modifier by applying it starting January 1, 2015 to payments under the Medicare PFS for physicians in groups of 100 or more eligible professionals. We identify a group of physicians as a single taxpayer identification number (TIN). For purposes of establishing group size only, we use the definition of an eligible professional as specified in section 1848(k) of the Act. We apply the value-based payment modifier to the Medicare paid amounts for the items and services billed under the PFS at the TIN level so that beneficiary cost-sharing is not affected. We apply the value-based payment modifier to the items and services billed by physicians under the TIN, not to other eligible professionals that also may bill under the TIN. We identify groups of physicians subject to the value-based payment modifier for CY 2015 based on a query of Medicare's Provider Enrollment, Chain, and Ownership System (PECOS) on October 15, 2013, and we remove any groups from this list if, based on a claims analysis, the group of physicians did not have 100 or more eligible professionals that submitted claims during the performance period (77 FR 69310).

We established CY 2013 as the performance period for the value-based payment modifier that will be applied to payments during CY 2015 and CY 2014 as the performance period for the value-based payment modifier that will be applied to payments in CY 2016 (77 FR 69314). We also finalized that we will not apply the value-based payment modifier in CYs 2015 and 2016 to any group of physicians that is participating in the Medicare Shared Savings Program, the Pioneer ACO model, or the Comprehensive Primary Care Initiative or other similar Innovation Center initiatives (77 FR 69313). From an operational perspective, we will apply this policy to any group of physicians in which one or more physician(s) participate(s) in one of these programs or initiatives during performance periods CY 2013 or CY 2014.

We finalized policies to determine the amount of the value-based payment modifier for CY 2015 by categorizing groups of physicians with 100 or more eligible professionals into two categories. Category 1 includes groups of physicians that either (a) self-nominate for the PQRS as a group and report at least one measure or (b) elect the PQRS Administrative Claims option as a group. Category 2 includes groups that do not fall within either of the two subcategories (a) or (b) of Category 1. Groups within Category 1 may elect to have their value-based payment modifier for CY 2015 calculated using the quality-tiering methodology, which could result in an upward, neutral, or downward adjustment amount. For groups that make this election, we use the performance rates on the quality measures reported through the PQRS reporting mechanism that the group selects for 2013 (that is, group practice reporting option (GPRO) web-interface, CMS-qualified registry, or PQRS Administrative Claims option) and the performance rates on three outcome measures to calculate the group's quality composite under the quality-tiering approach. If a group in Category 1 that elects quality-tiering self-nominates for the GPRO web-interface or CMS-qualified registry and does not meet the satisfactory reporting criteria for the PQRS incentive payment, we use the group's performance on the Administrative Claims option to calculate the group's quality composite under the quality-tiering approach. The value-based payment modifier for groups of physicians in Category 1 that do not elect-quality tiering is 0.0 percent, meaning that these groups will not receive a payment adjustment under the value-based payment modifier for CY 2015. Category 2 includes groups that do not fall within either of the two subcategories (a) or (b) of Category 1. For the groups that are in Category 2, the value-based payment modifier for the CY 2015 payment adjustment period is -1.0 percent.

We also finalized the following policies to calculate the value-based payment modifier using the quality-tiering approach. The quality-tiering approach requires creation of quality and cost composites for each group of physicians subject to the value-based payment modifier. The following brief summary describes the policies adopted in last year's final rule with comment

period (77 FR 69320 through 69326). To create the quality composite, we create a standardized score for each quality measure reported through the group's selected PQRS reporting mechanism, as well as the group's performance on three outcome measures (two composite measures of potentially preventable hospital admissions for acute and chronic conditions and a measure of all-cause hospital readmissions). The standardized score for each quality measure is calculated by dividing the difference between the group's performance rate and the measure's benchmark (the national mean of the measure's performance rate from the previous year) by the measure's standard deviation. The standardized scores for each measure are classified into one of six domains based on the national priorities related to clinical care, patient experience, population/community health, patient safety, care coordination, and efficiency established in the National Quality Strategy. Within each domain, we weight each measure's standardized score equally to arrive at a domain score. The domains are then equally weighted to form a quality of care composite. When a domain does not contain quality measures (for example, when a group chooses a reporting mechanism that does not contain measures in the domain), the remaining domains would be equally weighted to form the quality of care composite.

Additionally, we finalized a policy to construct the cost composite using five measures of total per capita costs for beneficiaries attributed to the group practice. The five measures are total per capita costs (both Parts A and B) and total per capita costs for beneficiaries with four specific chronic conditions: chronic obstructive pulmonary disease (COPD), heart failure, coronary artery disease (CAD), and diabetes. We attribute beneficiaries to each group using a two-step process that examines whether the group furnished the plurality (that is, more than any other group) of primary care services to the beneficiary. This attribution methodology is similar to the attribution rule we use for the Medicare Shared Savings Program and the PQRS GPRO web interface. We create a standardized score for each measure by dividing the difference between the group's performance rate and the measure's benchmark (the national mean of the measure's performance rate for the performance period) by the measure's standard deviation. We then classify each measure's standardized score into one of two domains: total per capita costs for all attributed beneficiaries (one measure) and total per capita costs for all attributed beneficiaries with specific conditions (four measures). Within each cost domain, each measure is equally weighted. In those instances in which we cannot calculate a particular cost measure because, for example, the number of cases is fewer than 20, we will weight the remaining cost measures in the domain equally. Similar to the quality of care composite, each cost domain is weighted equally to form the cost composite, unless one of the domains contains no measures, in which case the remaining domain will be weighted at 100 percent.

Under the quality-tiering approach, each group's quality and cost composites are classified into high, average, and low categories depending upon whether the composites are one or more standard deviations above or below the mean. We compare the group's quality of care composite classification with the cost composite classification to determine the value-based payment modifier adjustment for the CY 2015 payment adjustment period according to the amounts in Table 60.

TABLE 60—2015 VALUE MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost
High quality	+2.0x*	+1.0x*	+0.0%
Average quality	+1.0x*	+0.0%	-0.5%
Low quality	+0.0%	-0.5%	-1.0%

*Groups of physicians eligible for an additional +1.0x if (1) reporting Physician Quality Reporting System quality measures through the GPRO web-interface or CMS-qualified registry, and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

To ensure budget neutrality, we first aggregate the downward payment adjustments in Table 60 for those groups in Category 1 that have elected quality tiering with the −1.0 percent downward payment adjustments for groups of physicians subject to the value-based payment modifier that fall within Category 2. Using the aggregate downward payment adjustment amount, we then calculate the upward payment adjustment factor (×). These calculations will be done after the performance period has ended. Accordingly, because the performance period for the CY 2015 value-based payment modifier is CY 2013, these calculations will be performed after December 31, 2013.

This scoring methodology also provides an additional upward payment adjustment of +1.0x to groups of physicians that care for high-risk patients (as evidenced by the average HCC risk score of the attributed beneficiary population) and submit data on PQRS quality measures through PQRS via the GPRO using the web-interface or CMS-qualified registry. We will increase the upward payment adjustment from +2.0x to +3.0x for groups of physicians classified as high quality/low cost and from +1.0x to +2.0x for groups of physicians that are either high quality/average cost or average quality/low cost if the group of physicians' attributed beneficiary population has an average risk score that is in the top 25 percent of the distribution of beneficiary risk scores nationwide. This additional upward payment adjustment (+1.0x for the CY 2015 payment adjustment period) will not apply to groups of physicians that select the PQRS Administrative Claims reporting mechanism. Finally, we provide an informal review process to enable a group of physicians to inquire about the calculation of its value-based payment modifier.

Since adopting these policies, the Institute of Medicine released a new report, ''Interim Report of the Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Care: Preliminary Committee Observations,'' observing that to improve value, ''payment reforms need to create incentives to encourage behavioral change at the locus of care (providers and patient).'' [2] Our approach to implementing the value-based payment modifier is consistent with this vision because it ties a group practice's payment to its

[2] Institute of Medicine, ''Interim Report of the Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Health Care: Preliminary Committee Observations,'' (2013), p.29.

actions by rewarding high performing groups of physicians and penalizing low-performing groups of physicians.

On January 31, 2013, we submitted two cost measures—the total per capita costs for all attributed beneficiaries measure and the Medicare Spending per Beneficiary measure—to the National Quality Forum for endorsement. We have gained valuable feedback on a variety of issues (for example, attribution and risk adjustment) as we work with the National Quality Forum on the endorsement process for our cost measures. CMS is committed to refining our cost measures through future rulemaking based on feedback we receive from NQF and other stakeholders.

As discussed below in section K.5, we provided 2011 Quality and Resource Use Reports (QRURs) to 54 large group practices and to over 31,000 individual physicians in nine states that practice in group of physicians with 25 or more eligible professionals. These reports contained performance information on the quality of care furnished, and the cost of that care, to Medicare beneficiaries by these physicians and groups of physicians. Overall findings and results from these reports confirm that we can develop reliable and valid quality and cost measures at the group and individual physician level on which to base the value-based payment modifier. Moreover, group report recipients have found the reports informative and they have suggested ways to improve them to facilitate care coordination and quality improvement. We have adopted many of these suggestions in the QRUR reports that we plan to make available later this year.

4. Provisions of This Proposed Rule

In this proposed rule, we propose additions and refinements to the existing value-based payment modifier policies. These proposals continue our phased-in implementation of the value-based payment modifier by reinforcing our emphasis on quality measurement, alignment with the PQRS, physician choice, and shared accountability. Specifically, this proposed rule includes the following proposals:

- To apply the value-based payment modifier to groups of physicians with 10 or more eligible professionals in CY 2016.
- To make quality-tiering mandatory for groups within Category 1 for the CY 2016 value-based payment modifier, except that groups of physicians with between 10 and 99 eligible professionals would be subject only to any upward or neutral adjustment determined under the quality-tiering methodology, and groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments determined under the quality-tiering methodology.
- To increase the amount of payment at risk under the value-based payment modifier from 1.0 percent to 2.0 percent in CY 2016.
- To align the quality measures and quality reporting mechanisms for the value-based payment modifier with those available to groups of physicians under the PQRS during the CY 2014 performance period.
- To include the Medicare Spending Per Beneficiary (MSPB) measure in the total per capita costs for all attributed beneficiaries domain of the cost composite.
- To refine the cost measure benchmarking methodology to account for the specialties of the physicians in the group.

a. Group Size

In the CY 2013 PFS final rule with comment period, we stated that we would gradually phase in the value-based payment modifier in CY 2015 by first applying it to large groups (77 FR 69308), which we defined as groups of physicians with 100 or more eligible professionals. We noted our view that it would be reasonable to focus on groups with 100 or more eligible professionals before expanding the application of the value-based payment modifier to more groups and solo practitioners in CY 2016 and beyond.

To continue our phase-in of the value-based payment modifier, we believe it is appropriate to lower the group size threshold for CY 2016 payment adjustments, which will be based on performance during CY 2014. Table 61 shows the number of groups, eligible professionals (EPs) and physicians in groups of various sizes based on an analysis of calendar year 2011 claims with a 90-day run-out period. We note that the number of EPs includes other practitioners, such as physician assistants and nurse practitioners, in addition to physicians.

TABLE 61—ELIGIBLE PROFESSIONAL/PHYSICIAN GROUP SIZE DISTRIBUTION

[2011 claims]

Group size	Number of groups (TINs)	Eligible professionals	Number of physicians	Percent of physicians	Cumulative percentage
100+ EPs	1,132	311,094	215,936	25.7	25.7
50–99EPs	1,622	110,862	76,318	9.1	34.8
25–49 EPs	3,729	126,596	88,065	10.5	45.3
20–24 EPs	1,890	41,334	28,756	3.4	48.7
10–19 EPs	8,653	116,379	81,829	9.7	58.4
2–9 EPs	68,702	241,732	174.758	20.8	79.2
1 EP	222,097	222,097	175,115	20.8	100.0
Total	307,825	1,170,094	840,777	100	

We propose to apply the value-based payment modifier in CY 2016 to groups of physicians with 10 or more eligible professionals. We estimate that this proposal would cause approximately 17,000 groups (TINs) and nearly 60 percent of physicians to be affected by the value-based payment modifier in CY 2016. We believe this proposal continues our policy to phase in the value-based payment modifier by ensuring that the majority of physicians are covered in CY 2016 before it applies to all physicians in CY 2017. As discussed below in Section K.5, CMS conducted statistical reliability analyses on the PQRS quality measures and the cost measures contained in the 2010 and 2011 groups and individual Quality and Resource Use Reports (QRURs). These reports contained the same PQRS quality measures and cost measures that we will use for the value-based payment modifier. Both the quality and cost measures in the group reports were statistically reliable at a high level. Moreover, the average reliability score

was high for 98 percent of the individually reported PQRS measures and all of the cost measures (with a case size of at least 20) included in the individual feedback reports. Given these results, we believe that we can reliably apply a value-based payment modifier to groups of physicians with 10 or more eligible professionals in CY 2016 and to smaller groups and to solo practitioners in future years. Accordingly, we propose to revise the regulations at § 414.1210 to reflect that the CY 2016 value-based payment modifier would be applicable to physicians that are in groups with ten or more eligible professionals. We seek comments on this proposal.

We propose to identify groups of physicians that would be subject to the value-based payment modifier (for example, for CY 2016, groups of physicians with 10 or more eligible professionals) using the same procedures that we finalized in the CY 2013 PFS final rule with comment period (for a description of those procedures, we refer readers to 77 FR 69309 through 69310). Rather than querying Medicare's PECOS data base as of October 15 or another date certain, however, we propose to perform the query within 10 days of the close of the PQRS group self-nomination/registration process during the relevant performance period year. For example, for the CY 2016 value-based payment modifier, within 10 days of the close of the PQRS group self-nomination/registration process that will occur during the fall of CY 2014. We propose to revise the regulations at § 414.1210(c) to reflect that identification of the groups of physicians subject to the value-based payment modifier is based on a query of PECOS at the close of the PQRS registration period and that groups of physicians are removed from this list if, based on a claims analysis, the group of physicians did not have the required number of eligible professionals, as defined in § 414.1210(a), that submitted claims during the performance period for the applicable calendar year payment adjustment period. We seek comment on this proposal.

b. Approach to Setting the Value-Based Payment Modifier Adjustment Based on PQRS Participation

In the CY 2013 PFS final rule with comment period (77 FR 69311), we adopted a policy to categorize groups of physicians subject to the value-based payment modifier in CY 2015 based on a group's participation in the PQRS. Specifically, we categorize groups of physicians eligible for the CY 2015 value-based payment modifier into two categories. Category 1 includes groups that either (a) self-nominate for the PQRS as a group and report at least one measure or (b) elect the PQRS Administrative Claims option as a group for CY 2013. Groups of physicians in Category 1 may elect to have their value-based payment modifier for CY 2015 calculated using the quality-tiering methodology, which could result in an upward, neutral, or downward adjustment amount. The value-based payment modifier for groups of physicians in Category 1 that do not elect quality tiering is 0.0 percent, meaning that physicians in these groups will not receive a payment adjustment under the value-based payment modifier for CY 2015. Category 2 includes groups of physicians that do not fall within Category 1. For those groups of physicians in Category 2, the value-based payment modifier for CY 2015 is −1.0 percent.

We propose to use a similar two-category approach for the CY 2016 value-based payment modifier based on a group of physicians' participation in the PQRS but with different criteria for inclusion in Category 1. Category 2 would include those groups of physicians that are subject to the CY 2016 value-based payment modifier and do not fall within Category 1. Our proposal is intended to accommodate the various ways in which physicians can participate in the PQRS in CY 2014—either as a group practice participating in the PQRS GPRO or individually. We established in the CY 2013 PFS final rule with comment period that groups of physicians that wish to participate as a group in the PQRS during CY 2014 must self-nominate and select one of three PQRS GPRO reporting mechanisms: GPRO web interface, qualified registry, or EHR (77 FR 69199 through 69200 (Table 93)). We also established the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO for the PQRS payment adjustment for CY 2016 (77 FR 69200 through 69202) and we have proposed to modify these criteria as described in Table 27 of this proposed rule. In order to maintain alignment with the PQRS, for purposes of the CY 2016 value-based payment modifier, we propose that Category 1 would include those groups of physicians that meet the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO (through use of the web-interface, EHRs, or qualified registry reporting mechanisms) for the CY 2016 PQRS payment adjustment.

We understand that not all groups of physicians may want to participate in PQRS as a group under the GPRO in CY 2014. These groups of physicians may prefer to have all of their eligible professionals continue to report PQRS measures as individuals so that physicians and other eligible professionals in the group are able to report data on quality measures that reflect their own clinical practice. For example, a thoracic surgeon in a multi-specialty group practice may wish to report data on different quality measures than those on which a dermatologist or urologist in the same group practice may wish to report data. In addition, eligible professionals in these groups of physicians may wish to use different reporting mechanisms to report data for PQRS, such as the claims-based reporting mechanism, EHRs, qualified registries, or the proposed qualified clinical data registry reporting mechanism. Therefore, for the CY 2016 value-based payment modifier, we propose to include in Category 1 groups of physicians that do not self-nominate to participate in the PQRS as a group practice in CY 2014 and that have at least 70 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2016 PQRS payment adjustment. The criteria for satisfactory reporting by individual eligible professionals for the claims, qualified registry, and EHR reporting mechanisms for the CY 2016 PQRS payment adjustment were established in the CY 2013 PFS final rule with comment period (77 FR 69194 through 69195 (Table 91), 69200–69202). We are proposing in Table 25 of this proposed rule the criteria for satisfactory participation in a qualified clinical data registry and other proposed changes to the criteria for satisfactory reporting for the CY 2016 PQRS payment adjustment. Another way to state this proposal is that a group of physicians subject to the CY 2016 value-based payment modifier would be in Category 1 if at least 70 percent of the individual eligible professionals in the group avoid the CY 2016 PQRS payment adjustment by any of the reporting options available under the PQRS.

We are proposing a 70 percent threshold for three reasons. First, although we expect 100 percent of a group's eligible professionals to participate in PQRS, we believe that we will obtain a reliable indicator of the

group's quality if at least 70 percent of the eligible professionals in the group meet the criteria to avoid the PQRS payment adjustment. We recognize that many individual eligible professionals may be reporting data on PQRS measures for the first time in CY 2014 and we do not seek to impose too high a burden on these groups that does not increase the reliability of the group's quality performance data for purposes of the value-based payment modifier. Second, the vast majority of eligible professionals participate in the PQRS as individuals, not as members of a group practice. Third, based on an examination of 2011 PQRS data, at least 63 percent of groups of physicians (TINs) participating in the PQRS with fewer than 50 eligible professionals would meet the 70 percent threshold already. At a 70 percent threshold, however, only 29 percent of groups of physicians participating in the PQRS of more than 100 eligible professionals have at least 70 percent of their eligible professionals meeting the criteria for satisfactory reporting in 2011. We believe that this result is consistent with our policy to encourage group reporting by the very largest groups of physicians. Indeed, these large groups have several reporting mechanisms available under the PQRS GPRO including the web interface, registries, and EHRs. Accordingly, we also propose to revise the regulation text at § 414.1225, which was previously specific to the CY 2013 performance period and only referred to quality measures reported by groups of physicians rather than individual eligible professionals within a group. We seek comment on these proposals.

For a group of physicians that would be subject to the CY 2016 value-based payment modifier to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, in the case of the 70 percent option described above) would need to be met during the CY 2014 performance period for the PQRS CY 2016 payment adjustment. We note that any reporting periods that are established under the PQRS would continue to apply for purposes of the PQRS. In the event that the criteria that are finalized for the CY 2016 PQRS payment adjustment differ from what is proposed for the PQRS in this proposed rule, our intention is to align the criteria for inclusion in Category 1 to the extent possible with the criteria that are ultimately established for the CY 2016 PQRS payment adjustment.

We propose to more fully phase-in the quality-tiering methodology for calculating the value-based payment modifier for CY 2016 based on the number of eligible professionals in the group. We propose that groups in Category 1 would no longer have the option to elect quality tiering for the CY 2016 value-based payment modifier (as was the case for the CY 2015 value-based payment modifier) and instead would be subject to mandatory quality tiering. We propose to apply the quality-tiering methodology to all groups in Category 1 for the value-based payment modifier for CY 2016, except that groups of physicians with between 10 and 99 eligible professionals would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. In other words, we propose that groups of physicians in Category 1 with between 10 and 99 eligible professionals would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2016 value-based payment modifier. We believe this proposed approach would reward groups of physicians that provide high-quality/low-cost care, reduce program complexity, and more fully engage groups of physicians in our plans to implement the value-based payment modifier. Accordingly, we propose to revise the regulations at § 414.1270 to reflect the proposal to make the quality-tiering methodology mandatory, with the exception noted above, for all groups of physicians subject to the value-based payment modifier in CY 2016 that fall within Category 1. We seek comment on this proposal. We are also revising the regulations at § 414.1270 to clarify that for the CY 2015 payment adjustment period a group may be determined under the quality-tiering methodology to have poor performance based on low quality and high costs, low quality and average costs, or average quality and high costs.

For groups of physicians with 100 or more eligible professionals, we believe it is appropriate to begin to phase in both the upward and the downward payment adjustments under the quality-tiering methodology for the CY 2016 value-based payment modifier. Based on 2011 claims, we estimate that there are approximately 1,100 groups of 100 or more eligible professionals. We believe that such large groups should already be focused on quality improvement and that they have ample ability to do so. These groups should have developed the internal means to track and improve the quality of care they furnish to Medicare FFS beneficiaries. For example, several large group practices that have participated in the PQRS GPRO have redesigned their electronic medical records systems to capture data to continually monitor their performance on those quality measures and provide alerts at the point of care to physicians and practitioners to further facilitate provision of high quality care to Medicare beneficiaries. Moreover under the quality-tiering methodology for calculating the value-based payment modifier as we established in the CY 2013 PFS final rule with comment period and have updated in this proposed rule, groups of physicians that furnish high quality care will not have a downward adjustment, even if they furnish such care at high costs. Thus, we believe it is appropriate to apply both upward and downward adjustments under the quality-tiering methodology to groups of physicians with 100 or more eligible professionals in 2016. We seek comments on our proposals and, in the alternative, whether we should treat groups of physicians with 100 or more eligible professionals in the same manner as we propose to treat groups of physicians with between 10 and 99 eligible professionals under the quality-tiering methodology as described previously.

Accordingly, we propose to revise § 414.1270 to reflect these proposals, including our proposals regarding mandatory quality-tiering. We seek comment on these proposals.

c. Payment Adjustment Amount

Section 1848(p) of the Act does not specify the amount of payment that should be subject to the adjustment for the value-based payment modifier; however, section 1848(p)(4)(C) of the Act requires the value-based payment modifier be implemented in a budget neutral manner. Budget neutrality means that payments will increase for some groups of physicians based on high performance and decrease for others based on low performance, but the aggregate amount of Medicare spending in any given year for physicians' services will not change as a result of application of the value-based payment modifier.

In the CY 2013 PFS final rule with comment period, we adopted a modest payment reduction of 1.0 percent for groups of physicians in Category 1 that elected quality tiering and were classified as low quality/high cost and for groups of physicians in Category 2 (77 FR 69323–24). Although we received comments suggesting that larger payment adjustments (both

upward and downward) would be necessary to more strongly encourage quality improvements, we finalized our proposed adjustments as we believed they better aligned with our goal to gradually phase in the value-based payment modifier. However, we noted that as we gained experience with our value-based payment modifier methodologies, we would likely consider ways to increase the amount of payment at risk (77 FR 69324).

Since last year, we have further considered comments on ways to better encourage improvements in physician efficiency and quality while still gradually phasing in the value-based payment modifier. We agree with commenters on the value of gradually strengthening the incentives to improve performance by offering greater rewards for strong performance along with increased financial risk for poorer performance. As discussed below in section K.5, CMS conducted statistical reliability analysis on the PQRS quality measures and the cost measures contained in the 2010 and 2011 groups and individual physician feedback reports. These reports contained the same PQRS quality measures and cost measures that we will use for the value-based payment modifier. The quality and cost measures in the group reports were statistically reliable at a high level. Moreover, the average reliability score was high for 98 percent of the individually reported PQRS measures and for all of the cost measures (with a case size of at least 20) included in the individual feedback reports. Thus, we believe that we can increase the amount of payment at risk because we can reliably apply a value-based payment modifier in CY 2016 to groups of physicians with 10 or more eligible professionals and to smaller groups and to solo practitioners in future years. Therefore, we propose to increase the downward adjustment under the value-based payment modifier from 1.0 percent in CY 2015 to 2.0 percent for CY 2016. That is, for CY 2016, a −2.0 percent value-based payment modifier would apply to groups of physicians subject to the value-based payment modifier that fall in Category 2. In addition, we propose to increase the maximum downward adjustment under the quality-tiering methodology to −2.0 percent for groups of physicians classified as low quality/high cost and to set the adjustment to −1.0 percent for groups classified as either low quality/average cost or average quality/high cost. We propose to revise § 414.1270 and § 414.1275(c) and (d) to reflect the proposed increase to a 2.0 percent adjustment under the value-based payment modifier for the CY 2016 payment adjustment period. We are also making a technical correction to § 414.1275(c) to clarify the PQRS GPRO reporting mechanisms available in CY 2013. Table 62 shows the proposed quality-tiering payment adjustment amounts for CY 2016 (based on CY 2014 performance).

TABLE 62—2016 VALUE-BASED PAYMENT MODIFIER AMOUNTS

CY 2016			
Quality/cost	Low cost	Average cost	High cost
High quality	*+2.0x	*+1.0x	+0.0%
Average quality	*+1.0x	+0.0%	−1.0%
Low quality	+0.0%	−1.0%	−2.0%

*Groups of physicians eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

Consistent with the policy adopted in the CY 2013 PFS final rule with comment period, the upward payment adjustment factor (''x'') would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments. We note that any funds derived from the application of the downward adjustments to groups of physicians with 100 or more eligible professionals and the downward 2.0 percent adjustment applied to those groups of physicians subject to the value-based payment modifier that fall in Category 2, would be available to all groups of physicians eligible for value-based payment modifier upward payment adjustments. The quality-tiering methodology would continue to provide an additional upward payment adjustment of +1.0x to groups of physicians that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population). We seek comments on our proposal to increase the downward value-based payment modifier to 2.0 percent for those groups of physicians with 10 or more eligible professionals that are in Category 2 and for groups of physicians with 100 or more eligible professionals that are classified as low quality/high cost groups for the CY 2016 payment adjustment period.

d. Performance Period

In the CY 2013 PFS final rule with comment period (77 FR 69314), we adopted a policy that performance on quality and cost measures in CY 2014 will be used to calculate the value-based payment modifier that is applied to items and services for which payment is made under the PFS during CY 2016. We received comments requesting us to close the gap between the end of the performance period (for example, December 31, 2014) and the beginning of the payment adjustment period (for example, January 1, 2016), in order to strengthen the connection between the performance of physicians and groups of physicians and the financial incentives for quality improvement.[3] We understand that many private sector plans start to provide payment adjustment within seven months of close of the performance period.[4]

Because the payment adjustment periods for the value-based payment modifier are tied to the PFS, which is updated on an annual calendar year basis, options to close the one year gap between the close of the performance period and the start of the payment adjustment period center around altering the start and end dates of the performance period, and not the payment adjustment period. As discussed previously in this proposed rule, one option could be to adjust the performance period for quality data reported through the PQRS. In addition, we could calculate the total per capita

[3] See, e.g., Comment of the American College of Surgeons comment on the CY 2013 PFS proposed rule (Aug. 31, 2012).

[4] US GAO, Medicare Physician Payment: Private-Sector Initiatives Can Help Inform CMS Quality and Efficiency Incentive Efforts, GAO–13–160 (Dec. 2012), available at *http://www.gao.gov/assets/660/651102.pdf.*

cost measures on an April 1 through March 31 basis, thus closing the gap by three months.

However, a byproduct of altering the performance periods is that the deadline for submitting quality information would have to occur at the end of the performance period. In addition, the review period during which groups of physicians will be able to review the calculation of the value-based payment modifier would be shortened to allow the necessary system changes to implement the adjustment by the January 1 deadline for implementation of the annual PFS. We seek comment on the potential merits of altering our current performance periods.

Though we appreciate the comments requesting that we shorten the gap between the performance period and the payment adjustment period, we propose to use CY 2015 as the performance period for the value-based payment modifier adjustments that will apply during CY 2017. We believe it is important to propose the performance period for the payment adjustments that will apply in CY 2017, because section 1848(p)(4)(B)(iii) of the Act requires all physicians and groups of physicians to be subject to the value-based payment modifier beginning not later than January 1, 2017. Accordingly, we propose to add a new paragraph (c) to § 414.1215 to indicate that the performance period is CY 2015 for value-based payment modifier adjustments made in the CY 2017 payment adjustment period. We seek comment on this proposal.

We also are striving to provide more timely feedback to stakeholders regarding their cost and quality of care they furnish to Medicare beneficiaries. We note that in CY 2013, we plan to provide physician feedback reports (Quality and Resource Use Reports (QRURs)) starting in mid-September, which is eight and one-half months from the close of the CY 2012 reporting period (that is, December 31, 2012) and five months from the close of the quality data submission period (April 15, 2013) for the GPRO web interface. These QRURs will be made available to all groups of 25 or more eligible professionals and will preview how the groups of physicians would fare under the value-based payment modifier policies, albeit on CY 2012 data, that we established in the CY 2013 final rule with comment period. Moreover, we anticipate that these reports will contain actionable information regarding beneficiaries attributed to the group, thereby enabling physicians in the group to better coordinate care and improve the quality of care furnished. We also are in the process of enhancing our quality reporting and report dissemination infrastructure such that we expect to provide QRURs in 2014 even closer to the end of the performance period.

Despite these efforts, we expect there will always be a gap between the close of the performance period and the beginning of the payment adjustment period to account for various operational processes, albeit one that we are striving to reduce. During this gap, we allow for a three-month claim run out so that physicians are evaluated on complete and accurate information. We standardize the amounts on these claims in order to calculate the cost measures. This process takes one month. Concurrent with these two processes, we obtain the data reported for quality measurement and calculate the PQRS measures—a process which takes at least six months. In addition, we then calculate each group's cost and quality composites and implement the quality-tiering methodology. We then produce and verify the reports. These processes combined take approximately eight to nine months. We are striving to find ways to make these processes more efficient as we gain more experience producing these reports.

e. Quality Measures

In the CY 2013 PFS final rule with comment period (77 FR 69315), we aligned our policies for the value-based payment modifier for CY 2015 with the PQRS reporting mechanisms available to groups of physicians in CY 2013, such that data that a group of physicians submitted for quality reporting purposes through any of the PQRS group reporting mechanisms in CY 2013 would be used for calculating the quality composite under the quality-tiering approach for the value-based payment modifier for CY 2015. Moreover, all of the quality measures for which groups of physicians are eligible to report under the PQRS are used to calculate the group of physicians' value-based payment modifier for CY 2015, to the extent the group of physicians submits data on such measures. We also established a policy to include three additional quality measures (outcome measures) for all groups of physicians subject to the value-based payment modifier: (1) A composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia, and (3) rates of an all-cause hospital readmissions measure (77 FR 69315).

We believe it is important to continue to align the value-based payment modifier for CY 2016 with the requirements of the PQRS, because quality reporting is a necessary, but not sufficient, component of quality improvement. We also seek not to place an undue burden on physicians to report such data so that they can furnish care to beneficiaries in an efficient manner. We propose to include, therefore, for purposes of the value-based payment modifier for CY 2016, all of the PQRS GPRO reporting mechanisms available to group practices for the PQRS reporting periods in CY 2014 and all of the PQRS reporting mechanisms available to individual eligible professionals for the PQRS reporting periods in CY 2014. Accordingly, we also propose to update our regulations at § 414.1220 to reflect this proposal. We note that the criteria for satisfactory reporting of data on PQRS quality measures for individual eligible professionals via qualified registries for the CY 2014 PQRS incentive and CY 2016 PQRS payment adjustment permits the use of a 6-month reporting period (Tables 24 and 25). We believe that data submitted via qualified registries for this 6-month reporting period would be sufficiently reliable on which to base a group of physicians' quality composite score under the value-based payment modifier because in order for us to use the data to calculate the score, we would require data for each quality measure on at least 20 beneficiaries, which is the reliability standard for the value-based payment modifier (77 FR 69322–69323). Given this level of reliability, we believe a six-month reporting period would be comparable to a 12-month reporting period for the purpose of evaluating the quality of care furnished by a group of physicians subject to the value-based payment modifier. We seek comment on this proposal.

We also propose to utilize all of the quality measures that are available to be reported under these various PQRS reporting mechanisms, including quality measures reported through qualified clinical data registries, to calculate a group of physicians' value-based payment modifier in CY 2016 to the extent that a group of physicians submits data on these measures. In addition, we propose that groups of physicians with 25 or more eligible professionals will be able to elect to have included in their value-based payment modifier for CY 2016 the patient experience of care measures collected through the PQRS CAHPS

survey for CY 2014. These reporting mechanisms and the patient experience measures are described in Tables 24 through 27. We note that the three outcome measures that we finalized in the CY 2013 PFS final rule with comment period and in § 414.1230—the two composites of rates of potentially preventable hospital admissions and the all-cause hospital readmission measure—would continue to be included in the quality measures used for the value-based payment modifier in CY 2016.

Although we have received comments to require a core set of quality measures for the value-based payment modifier, we believe it is premature to require reporting on limited set of measures by all physicians until physicians have had a chance to choose measures that are meaningful to their practice. As we indicated previously, our primary focus is on measurement and alignment during the phase-in of the value-based payment modifier, because we believe it is difficult to maintain high-quality care and improve quality and performance without measurement. Thus, it is important to provide physicians and groups of physicians flexibility on the data they report for quality measures.

For those groups of physicians subject to the value-based payment modifier in CY 2016 whose eligible professionals participate in the PQRS as individuals rather than as a group practice under the GRPO (that is, groups of physicians that are assessed under the 70 percent threshold), we propose to calculate the group's performance rate for each measure reported by at least one eligible professional in the group of physicians by combining the weighted average of the performance rates of those eligible professionals reporting the measure. If all of the eligible professionals in a group of physicians subject to the CY 2016 value-based payment modifier satisfactorily participate in a PQRS qualified clinical data registry in CY 2014 and we are unable to receive quality performance data for those eligible professionals for the reasons discussed above, for purposes of the value-based payment modifier, we propose to classify the group's quality composite score as ''average'' under the quality-tiering methodology, because we would not have data to reliably indicate whether the group should be classified as high or low quality under the quality-tiering methodology. Accordingly, we also propose to add a new subsection to our regulations at § 414.1270 to reflect our proposals about how to assess quality performance for groups assessed under the 70 percent threshold. We seek comment on these proposals.

We note that when the value-based payment modifier applies to all physicians and groups of physicians in CY 2017 based on performance during CY 2015, we anticipate continuing our policy to align with the PQRS group reporting for all groups of physicians of two or more eligible professionals, and we anticipate permitting physicians who are solo practitioners to use any of the PQRS reporting mechanisms available to them under the PQRS for reporting periods in CY 2015 for purposes of the value-based payment modifier in CY 2017. Although we are not proposing to adopt this policy in this proposed rule, we seek comment on this approach to align the quality measures and reporting mechanisms used in the PQRS for purposes of the value-based payment modifier.

f. Inclusion of the Medicare Spending per Beneficiary Measure in the Value-Based Payment Modifier Cost Composite

In the CY 2013 PFS final rule with comment period (77 FR 69316), we established a policy to include five cost measures in the value-based payment modifier cost composite. The five measures are total per capita costs (both Parts A and B) and total per capita costs for beneficiaries with four specific chronic conditions: Chronic obstructive pulmonary disease (COPD), heart failure, coronary artery disease (CAD), and diabetes. We stated that the value-based payment modifier should incorporate additional measures that are consistent with the National Quality Strategy and other CMS quality initiatives. As a step toward that goal, beginning with the CY 2016 value-based payment modifier, we propose to expand the cost composite to include an additional measure, the Medicare Spending per Beneficiary (MSPB) measure (with one modification as discussed below). This section discusses the background of the MSPB measure and our proposals to incorporate it into the value-based payment modifier beginning with the CY 2016 payment adjustment period and beyond.

Background on the implementation of the MSPB measure for other CMS quality programs. We finalized the MSPB measure for use in the Hospital IQR Program in the FY 2012 IPPS final rule to further Medicare's transformation from a system that rewards volume of service to one that rewards efficient, effective care and reduces delivery system fragmentation and to help address the critical issue of health care costs (76 FR 51618–27). We finalized the MSPB measure for inclusion in the Hospital VBP Program in the FY 2013 IPPS final rule as an important first step toward identifying value in healthcare. In that rule, we expressed our belief that this measure provides an incentive for hospitals to build stronger relationships with and better understand the providers and suppliers that furnish care for their patients before and after an acute care hospitalization (77 FR 53585). When viewed in light of other quality measures, as a part of the value-based payment modifier measure set, we believe that the measure would enable us to align incentives and similarly recognize physician groups involved in the provision of high-quality care at a lower cost to Medicare. This measure also addresses physician care associated with acute inpatient hospitalizations and post-acute care. In its recently-released ''Interim Report of the Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Care: Preliminary Committee Observations,'' the Institute of Medicine (IOM) observed that, ''Geographic variation in total Medicare spending is strongly influenced by the utilization of post-acute care.'' [1] Medicare spending post-hospital discharge is a significant source of variation in the MSPB measure rates, with spending unrelated to readmissions being the largest source of variation in those post-discharge Medicare payments. As part of the value-based-payment modifier measure set, the MSPB measure would recognize and enable CMS to assess groups of physicians' performance relating to post-acute care spending, which is a ''major source of unexplained variation in Medicare spending.'' [1]

We propose that this measure would be added to the total per capita costs for all attributed beneficiaries domain of the value-based payment modifier. Thus, there would be two measures in the total per capita costs for all attributed beneficiaries domain—the total per capita costs measure and the MSPB measure—each weighted equally in the domain. We considered placing this measure in the total per capita costs for all attributed beneficiaries with specific conditions domain; however, we are not proposing to do so because the MSPB measure is similar to the total per capita costs measure (because it includes all costs incurred by a beneficiary), albeit one that is related to the totality of services furnished surrounding an inpatient hospitalization, and thus belongs in the total per capita costs for all attributed beneficiaries domain. Moreover, we intend to propose in future rulemaking

to replace the four measures in the total per capita costs for all attributed beneficiaries with specific conditions domain with cost measures derived from the CMS Episode Grouper and other episode-based costs derived from our recent and ongoing work with many specialty societies.[5] We solicit comments on these potential changes to the condition-specific cost measures as well as on the other elements of the cost composite in preparation for the CY 2015 performance period affecting payment adjustment year CY 2017.

We currently use the MSPB measure in two other CMS quality initiatives, the Hospital Inpatient Quality Reporting (IQR) and Hospital Value-Based Purchasing (VBP) Programs. We believe that its inclusion in the value-based payment modifier will help to align performance incentives across the delivery system. By focusing on the cost of care and encouraging avoidance of unnecessary services, the measure also addresses one of the National Quality Strategy aims of better care: Care that is affordable. This measure has been submitted to the National Quality Forum for endorsement, and it was supported by the Measures Application Partnership for inclusion in both the Hospital IQR and VBP Programs.

Construction of the MSPB measure. The MSPB measure used for the Hospital IQR and VBP Programs is constructed of services furnished surrounding hospitalizations (''index admissions''). The measure includes all Medicare Part A and Part B payments during an MSPB episode. An MSPB episode spans from 3 days prior to an index admission at a subsection (d) hospital[6] through 30 days post discharge with certain exclusions. Certain hospitalizations at subsection (d) hospitals do not represent index admissions for the MSPB measure. Admissions that result in a transfer from one acute hospital to another, episodes that occur fewer than 30 days before the end of the performance period, or episodes during which the beneficiary is not enrolled in both Part A and Part B Medicare do not count as index admissions. Costs for each episode are risk adjusted for age and severity of illness, and the included payments are standardized to remove differences attributable to geographic payment adjustments and other payment factors. The payment standardization is the same methodology used for the existing total per capita cost measures included in the value-based payment modifier.

To calculate a hospital's MSPB amount, the payment-standardized costs for all index admissions are summed and divided by the sum of the expected costs from the risk adjustment model. This ratio is then multiplied by the national average MSPB episode cost to give the hospital's MSPB amount. Because the Hospital IQR and VBP Programs apply to subsection (d) hospitals, we attribute a MSPB index admission to the hospital at which an index admission occurs, and we calculate the MSPB amount at the hospital level.

After determining an individual hospital's MSPB amount, we divide it by the national median MSPB amount to calculate a ratio. This ratio is then converted to a percentage which is the MSPB measure rate that we report publicly on Hospital Compare under the Hospital IQR Program and use to generate a measure score for the Efficiency domain under the Hospital VBP Program. In the context of the value-based payment modifier, we propose a slightly revised calculation. We propose not to convert the MSPB amount to a ratio as is done to compute a hospital's MSPB measure, but rather use the MSPB amount as the measure's performance rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627) for a detailed description of the MSPB measure that is used in the Inpatient Quality Reporting program and the HVBP program. Additional information on the measure, including a detailed specification document (entitled ''MSPB Measure Information Form'') and the payment standardization methodology (entitled ''CMS Price Standardization'') can be found in the ''Measure Methodology'' section at *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*. We seek comment on our proposals to include the MSPB measure (as modified per the discussion above) in the value-based payment modifier cost composite and to add the measure to the total per capita costs for all attributed beneficiaries domain. We also propose to revise the regulations at § 414.1235 to include the Medicare Spending per Beneficiary measure in the set of cost measures for the value-based payment modifier and § 414.1260(b)(1)(i) to include the Medicare Spending per Beneficiary measure in the total per capita costs for all attributed beneficiaries domain. As stated previously, all of our proposals related to the MSPB measure would apply beginning with the CY 2016 value-based payment modifier.

Attribution of the MSPB measure to physician groups. Unlike the Hospital IQR and VBP Programs, in which we attribute the MSPB index admission to the hospital at which the index admission occurred, we need to develop a method to attribute the MSPB episode to groups of physicians to include the measure in the value-based-payment modifier. We propose to attribute an MSPB episode to a group of physicians subject to the value-based payment modifier (as identified by a single TIN), when any eligible professional in the group submits a Part B Medicare claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the performance period for the applicable calendar year payment adjustment period. Thus, the same index admission and MSPB episode could be attributed to more than one group of physicians.

We believe that attribution of the MSPB episode to all groups of physicians from which an eligible professional submits a Part B claim for a service rendered during the hospitalization is the best way to assign responsibility for, and encourage greater coordination of, care furnished to Medicare beneficiaries who are hospitalized. Based on CY 2011 claims data, the proposed approach would enable approximately 11,419 groups of physicians with at least 10 eligible professionals to have an MSPB measure score included in their cost composite.[7] Our proposed approach incentivizes hospitals and physicians to furnish efficient, effective care during a hospitalization and to coordinate post-discharge care to avoid unnecessary services and preventable readmissions. Further, we believe that this attribution approach fosters shared accountability between hospitals and physicians for the care they furnish to Medicare beneficiaries who are hospitalized. We propose to add a new paragraph (b) to § 414.1240 to indicate that a MSPB episode would be attributed to a group

[5] Our recent activities relating to developing Medicare-specific episodes using the CMS Episode grouper and development of other episode costs are discussed in the Physician Feedback Program section below.

[6] Section 1886(d)(1)(B) of the Social Security Act defines such hospitals as those in the 50 States and the District of Columbia other than psychiatric hospitals, rehabilitation hospitals, hospitals whose inpatients are predominantly under 18 years old, hospitals whose average inpatient length of stay exceeds 25 days, and hospitals involved extensively in treatment for, or research on, cancer.

[7] We note that, based on 2011 claims, many of these 11,419 groups would only have the MSPB measure included in the cost composite because the physicians in the groups do not provide primary care services and thus do not have attributed beneficiaries for the five annual total per capita cost measures.

of physicians subject to the value-based payment modifier if any eligible professional in the group submits a Part B Medicare claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the performance period for the applicable calendar year payment adjustment period. Groups of physicians would have a Medicare Spending per Beneficiary measure score included in their cost composite based on the proposed attribution methodology for the MSPB. We welcome public comment on our proposal.

We also considered attributing the MSPB episode to physician groups from which an eligible professional in the group billed a part B claim for a service rendered at any time during the Medicare Spending per Beneficiary episode (that is, from 3 days prior to an index admission through 30 days post-discharge). This attribution approach would place an even stronger emphasis on shared accountability for care provided to Medicare beneficiaries who are hospitalized, both during and after their hospitalization. Based on 2011 claims data, we estimate that attribution to any physician group from which a eligible professional billed a part B claim at any time during the episode would enable an additional 3,017 groups of physicians with 10 or more eligible professionals to receive an MSPB measure performance rate for inclusion in the cost composite, as compared to our proposed attribution approach which considers only those eligible professionals who bill a Part B claim during the hospitalization. We welcome public comment on the alternative attribution approach under which we would attribute an MSPB episode to a physician group if any eligible professional in the group billed a Part B service during the 3 days prior to an index admission through 30 days post hospital discharge.

In addition to the proposed attribution method above, we considered several other methods to attribute the MSPB measure to physician groups. For example, the MSPB episode could be attributed solely to the group of physicians that provided the plurality of Part B services billed either: (1) During the entire MSPB episode (that is three days prior to hospital admission through 30 days post discharge); or (2) during the index hospitalization only. By ''plurality'' of services, we mean the highest total dollar amount paid by Medicare to any group of physicians who provided Part B services during a given portion of an episode (either the full episode or the hospitalization only). The group of physicians need not have provided the majority of the services paid by Medicare during a given portion of an episode, but rather to have provided services for which Medicare paid more than it did to any other group of physicians during that portion of an episode. This method is a single attribution approach unlike our proposal which is a multi-attribution approach.

Using 2011 claims, we analyzed the number of TINs, comprised of 10 or more eligible professionals, that would be attributed an MSPB measure rate under these alternative attribution methods given a minimum of 20 MSPB episodes required. Our analyses revealed that 7,799 TINs (out of approximately 17,000 TINs (see Table 61)) would be eligible to receive an MSPB measure rate, if MSPB episodes were attributed to the group of physicians that received the plurality of Medicare Part B payments during the entire MSPB episode. This represents a 46% decrease from the 11,419 TINs that would receive an MSPB measure rate, were it attributed to a group from which an eligible professional rendered any Part B service during the entire episode, as we proposed above. Our analysis also showed that 7,582 TINs would be eligible to receive an MSPB measure rate, if MSPB episodes were attributed to the physician group that billed the plurality of Medicare Part B payments during the index admission. This represents a 34% decrease from the 14,436 TINs that would receive an MSPB measure rate, were it attributed to a group from which an eligible professional rendered any Part B service during the index admission.

We considered these attribution methods because they represent methods to identify groups of physicians that were ''most responsible'' for the Part B Medicare payments made during the episode. We are not proposing these methods, because we believe our proposed multiple attribution approach better incentivizes a team approach to accountability for Medicare beneficiaries' care during a hospitalization. We believe our proposed attribution approach is further supported by the higher number of TINs that will be able to receive an MSPB measure rate under that methodology. We seek comment, however, on these two single alternative attribution approaches we considered: Attributing an MSPB episode to the group of physicians that provided the plurality of Part B services billed either during the entire MSPB episode or during the index hospitalization only.

In addition, we considered a hybrid attribution method: Attribute MSPB episodes to all TINs from which an eligible professional provided services representing at least 35 percent of the total Medicare Part B payments made either: (1) During the entire MSPB episode (that is three days prior to hospital admission through 30 days post discharge); or (2) during the index hospitalization only. This alternative could result in multiple attribution, if two eligible professionals from different TINs each provided services representing at least 35 percent of the Part B Medicare payments during one of the episode portions described above (either the full episode or during the index admission only). The rationale for this attribution approach is that it ensures that a group of physicians had responsibility for a significant portion of the Medicare beneficiary's care during a given portion of the MSPB episode. We are not proposing this alternative, because we believe that our proposed attribution approach better incentivizes a team approach to accountability for Medicare beneficiaries' care during and after a hospitalization. We welcome public comment on this alternative attribution approach based on provision of services representing at least 35 percent of Medicare Part B payments made either during the entire MSPB episode or during the index hospitalization only.

Reliability standard for the Medicare Spending per Beneficiary measure for the value-based payment modifier. We propose that a group of physicians would have to be attributed a minimum of 20 MSPB episodes during the performance period to have their performance on this measure included in the value-based payment modifier cost composite. Table 63 shows the MSPB measure's reliability at various minimum numbers of episodes for all Medicare-enrolled TINs with at least one EP (not just TINs of 10 or more eligible professionals) from May 2011 through December 2011. In this context, reliability is defined as the extent to which variation in the measure's performance rate is due to various in the cost of services furnished by groups of physicians rather than random variation due to the sample of cases observed. Potential reliability values range from zero to one, where one (highest possible reliability) signifies that all variation in the measure's rates is the result of variation in the difference is performance across groups of physicians. Generally, reliabilities in the 0.40–0.70 range are often considered

moderate and values greater than 0.70 high.

TABLE 63—RELIABILITY OF MEDICARE SPENDING PER BENEFICIARY MEASURE FOR ALL TINS WITH AT LEAST ONE ELIGIBLE PROFESSIONAL

[May 2011–December 2011]

MSPB episodes attributed	Number of TINs	Percent of TINs	Mean risk-adjusted standardized cost per MSPB episode	Average reliability
1–9	59,419	47	$20,493	0.65
10–19	12,332	10	21,260	0.79
20–29	7,774	6	21,225	0.83
30–39	5,839	5	21,340	0.85
40–49	4,511	4	21,324	0.87
50–99	12,648	10	21,353	0.89
100–124	3,702	3	21,403	0.91
125–149	2,761	2	21,342	0.92
150–174	2,134	2	21,316	0.93
175–199	1,673	1	21,119	0.93
200+	14,933	12	20,562	0.96

We also considered a minimum number of 10 episodes. The advantage of this lower minimum number is that it would enable us to calculate the MSPB measure for an additional 12,332 physician groups once we apply the value-based payment modifier to all physicians and groups of physicians. With a minimum of 10 cases, the measure is still very reliable, as illustrated in the Table 63. We are proposing the minimum of 20 cases for initial implementation of this measure in the cost composite beginning with the CY 2016 value-based payment modifier because it strikes a balance between maintaining high reliability and including a large number of physician groups. We note that this reliability standard we are proposing is the same one we adopted in the CY 2013 PFS final rule with comment period that applies to quality and cost measures used in the value-based payment modifier (77 FR 69323). We welcome public comment on our proposed minimum of 20 episodes for inclusion of the Medicare Spending per Beneficiary measure in the cost composite for the value-based payment modifier and on the alternative 10 episode minimum that we considered.

g. Refinements to the Cost Measure Composite Methodology

In the CY 2013 PFS final rule with comment period (77 FR 69322), we established a policy to create a cost composite for each group of physicians subject to the value-based payment modifier that includes five payment-standardized and risk-adjusted cost measures. To calculate the each group's cost measures, we first attribute beneficiaries to the group of physicians. We attribute beneficiaries using a two-step attribution methodology that is used for the Medicare Shared Savings Program and the PQRS GPRO and that focuses on the delivery of primary care services (77 FR 69320). We have observed that groups of physicians that do not provide primary care services are not attributed beneficiaries or are attributed fewer than 20 beneficiaries and, thus, we are unable to calculate reliable cost measures for those groups of physicians (77 FR 69323). Given this development, we propose that, to the extent that we are unable to attribute a sufficient number of beneficiaries to a group of physicians subject to the value-based payment modifier and thus are unable to calculate any of the cost measures with at least 20 cases, the group of physicians' cost composite score would be classified as ''average'' under the quality-tiering methodology. We believe this policy is reasonable because we would have insufficient information on which to classify the group of physicians' costs as ''high'' or ''low'' under the quality-tiering methodology. Moreover, we believe that to the extent a group of physicians' quality composite is classified as ''high'' or ''low,'' the groups of physicians' value-based payment modifier should reflect that classification. Accordingly, we propose to add a new paragraph at § 414.1270 to reflect this proposal that groups of physicians in Category 1 for which we attribute fewer than 20 cases to calculate any cost measure would have their cost composite classified as ''average'' cost. We seek comment on this proposal.

Once we calculate the cost measures for each group of physicians subject to the value-based payment modifier, we create the cost composite by calculating a standardized score for each cost measure and then placing the measures into one of two equally weighted domains: (1) The total per capita costs for all attributed beneficiaries domain; and (2) the total per capita costs for attributed beneficiaries with specific conditions domain. This standardized score is referred to in statistical terms as a Z-score. To arrive at the standardized score for each cost measure, we compare the performance for each group's cost measures to the benchmark (national mean) of other groups subject to the value-based payment modifier (peer group) for the same performance year. Specifically, we calculate the benchmark for each cost measure as the national mean of the performance rates among all groups of physicians to which beneficiaries are attributed and that are subject to the value-based payment modifier. For example, for CY 2015, the cost measures of groups of 100 or more eligible professionals (EPs) will be compared to the cost measures of other groups of 100 or more EPs. We also noted that we would consider the effects of this policy over the next several years as we implement this program and may consider changes to these policies through future rulemaking.

Using 2011 claims data, we have since examined the distribution of the overall total per capita cost measure among all groups of physicians with one or more eligible professionals to determine whether comparisons at the group level would be appropriate once we apply the value-based payment modifier to smaller groups of physicians and solo practitioners. We found that our current peer grouping methodology could have varied impacts on groups of physicians

that are comprised of different physician specialties. This result occurs because the peer group for the per capita cost benchmarks is based on a national mean calculated among all groups of physicians subject to the value modifier rather than determined more narrowly (for example, within a physician specialty).

For certain physician specialties, the types of services furnished typically have higher than average or lower than average costs, and thus can affect the group's cost measures. For example, medical and other types of oncologists tend to treat relatively costly beneficiaries and bill for expensive Part B drugs, which can increase mean total per capita costs for oncologists as a whole. By contrast, dermatologists and ophthalmologists, for example, perform relatively low cost procedures in an outpatient setting and, thus, their total per capita cost measures are low. Moreover, to the extent that physicians in groups of physicians work together to provide services to the same beneficiaries, groups of physicians with a large proportion of high or low-cost specialists can affect the level of the group's cost measures. Although the cost data are adjusted to account for the relative risk of patients, the effects of these adjustments do not fully offset this result at the physician and physician group level.

To address this issue beginning with the CY 2016 value-based payment modifier, we considered two methods that account for the group practice's specialty composition so that our quality-tiering methodology produces fair peer group comparisons and, ultimately, correctly ranks group of physicians based on actual performance. Taking account of physician specialties in making cost comparisons is similar to the approach we have used in the CY 2010 and CY 2011 Quality and Resource Use Reports (QRURs) for individual physicians in which we made cost comparisons at the individual physician specialty level.

The first method, ''specialty adjustment,'' accounts for the specialty composition of the group prior to computing the standardized score for each cost measure. This method enables us to develop comparable benchmarks for the risk-adjusted cost measures against which to evaluate groups of physicians of smaller size who often have fewer or single specialty composition. More specifically, we would adjust the standardized score methodology to account for a group's specialty composition using three steps:

Step 1: Create a specialty-specific expected cost based on the national average for each cost measure (referred to as the ''national specialty-specific expected costs''). To do so, we would attribute beneficiaries to a group using the plurality of primary care services methodology that we finalized in the CY 2013 PFS final rule with comment period (77 FR 69316). For each specialty, we would calculate the average cost of beneficiaries attributed to groups of physicians with that specialty, weighted by the number of EPs in each group.

Step 2: Calculate the ''specialty-adjusted expected cost'' for each group of physicians by weighting the national specialty-specific expected costs by the group's specialty composition of Part B payments. That is, the specialty-adjusted expected cost for each group is the weighted average of the national specialty-specific expected cost of all the specialties in the group, where the weights are each specialty's proportion of the group's Part B payments. The Part B payments for each specialty are determined based on the payments to each EP in the group, and each EP is identified with one specialty based on its claims.

Step 3: Divide the total per capita cost by the specialty-adjusted expected cost, and multiply this ratio by the national average per capita cost so that we can convert this ratio to a dollar amount (referred to as the ''specialty-adjusted total per capita cost'') that can then be used in the standardized (Z-) score to determine whether a group can be classified as high cost, low cost, or average.

Below, we illustrate the three steps of the specialty adjustment to the standardized score with an example. Assume for simplicity that only two TINs and two specialties exist: TIN 1 and TIN 2, and Specialty A and Specialty B. For this example, assume that the total per capita costs and specialty shares are as shown in Table 64.

TABLE 64—EXAMPLE OF CALCULATING SPECIALTY-ADJUSTED TOTAL PER CAPITA COST: ASSUMPTIONS

TIN	Risk-Adjusted per capita cost	Number of attributed beneficiaries	Number of EPs in TIN by specialty type A or B	Specialty share of EPs in TIN	Specialty share of part B payments in TIN
TIN 1	$12,000	1,500	A: 10; B: 30	A: 25%; B: 75%	A: 35%; B: 65%
TIN 2	8,000	2,000	A: 21; B: 39	A: 35%; B: 65%	A: 60%; B: 40%

Step 1: To compute the national specialty-specific expected cost for a specialty across all TINs, we first calculate the numerator, which is the product of each TIN's total per capita cost times its weight (the number of attributed beneficiaries times that specialty's share of the TIN's EPs times the number of EPs of that specialty in that TIN), summed across all TINs. This sum is divided by the denominator, which is the sum across all TINs of the same weights that were used in the numerator. For this example, the national specialty-specific expected cost for Specialty A is ($12,000 * 1,500 * 25% * 10 + $8,000 * 2,000 * 35% * 21)/(1,500 * 25% * 10 + 2,000 * 35% * 21) = $8,813. Similarly, the national specialty-specific expected cost for Specialty B is ($12,000 * 1,500 * 75%*30 + $8,000 * 2,000 * 65% * 39)/(1,500 * 75% * 30 + 2,000 * 65% * 39) = $9,599.

National Specialty-Specific Expected Cost, by Specialty (step 1)

Specialty A: $8,813

Specialty B: $9,599

Step 2: To calculate the specialty-adjusted expected cost for each group (TIN), we would multiply the above national specialty-specific expected costs by each group's proportion of specialty-specific Part B payments. For each TIN, we compute the product of the TIN's proportion of specialty-specific Part B payments, summed across all specialty types of the TIN. In our example, the specialty-adjusted expected cost for TIN 1 would be computed as 35% * $8,813 + 65% * $9,599 = $9,324. Similarly, the specialty-adjusted expected cost for TIN 2 would be 60% * $8,813 + 40% * $9,599 = $9,127.

Specialty-Adjusted Expected Cost, by TIN (step 2)

TIN 1: $9,324

TIN 2: $9,127

Step 3: We divide the total per capita cost by the specialty-adjusted expected cost and multiply this ratio by the national average per capita cost, to convert this ratio to a dollar amount.

Assuming the national average per capita cost is $9,714, we can compute the specialty-adjusted total per capita cost for each TIN, as shown in Table 65.

TABLE 65—EXAMPLE OF CALCULATING SPECIALTY-ADJUSTED TOTAL PER CAPITA COST: CALCULATIONS

COLUMN	A	B	C	D
TIN	Total per capita cost	Specialty-adjusted expected cost	National average per capita cost	Specialty-adjusted total per capita cost: ((column A/ column B) * column C)
TIN 1	$12,000	$9,324	$9,714	$12,502
TIN 2	8,000	9,127	9,714	8,514

The figure in the rightmost column (column D) is the specialty-adjusted total per capita cost that is used to compute a group's standardized (Z-) score. As can be seen, the specialty-adjusted total per capita cost for use in the standardized score is $12,502 for TIN 1 and $8,514 for TIN 2.

To illustrate the impact of the specialty adjustment methodology, we examined the distribution, by specialty, of the overall specialty-adjusted total annual per capita cost measure based on 2011 claims for group of physicians with 1 or more eligible professionals. Table 66 includes the percentage of physicians in each specialty that practice in groups of 1 or more eligible professionals with 20 or more attributed beneficiaries and that, based only on this one measure, would be classified into low, average, and high cost groups. Table 66 does not represent all of the physicians within that specialty, rather only those that practice in groups of physicians with at least 20 attributed beneficiaries.

TABLE 66—PERCENTAGE OF PHYSICIANS PRACTICING IN GROUPS WITH 1 OR MORE ELIGIBLE PROFESSIONALS, WITH AT LEAST 20 BENEFICIARIES, CLASSIFIED BY COST

Specialty	Percentage of eligible professionals in groups (TINs) classified as		
	Low cost (percent)	Average cost (percent)	High cost (percent)
Addiction medicine	4.7	94.1	1.2
Allergy/immunology	5.3	92.4	2.3
Anesthesiology	1.6	93.5	4.9
Cardiac Electrophysiology	1.9	95.7	2.4
Cardiac surgery	0.5	92.9	6.6
Cardiology	4.4	92.2	3.3
Chiropractic	3.1	88.7	8.2
Colorectal surgery	3.1	89.2	7.6
Critical care (intensivists)	1.7	91.9	6.4
Dermatology	30.6	68.0	1.4
Diagnostic radiology	0.7	92.7	6.6
Emergency medicine	3.7	89.1	7.2
Endocrinology	9.2	89.1	1.7
Family practice	1.3	91.7	7.0
Gastroenterology	4.4	93.3	2.2
General practice	5.7	84.8	9.5
General surgery	1.6	90.1	8.3
Geriatric medicine	1.5	83.8	14.7
Geriatric Psychiatry	0.0	82.5	17.5
Gynecologist/oncologist	1.7	88.5	9.8
Hand surgery	3.1	95.6	1.3
Hematology	0.7	89.1	10.2
Hematology/oncology	1.0	87.3	11.8
Hospice and Palliative Care	0.3	87.9	11.8
Infectious disease	2.5	90.6	6.9
Internal medicine	1.3	87.4	11.3
Interventional Pain Management	2.9	89.7	7.4
Interventional radiology	0.7	93.0	6.2
Maxillofacial surgery	0.9	94.7	4.4
Medical oncology	0.5	83.4	16.1
Nephrology	7.6	89.3	3.0
Neurology	5.0	92.4	2.6
Neuropsychiatry	4.0	90.7	5.3
Neurosurgery	1.4	83.7	14.9
Nuclear medicine	2.2	90.5	7.3
Obstetrics/gynecology	7.7	89.0	3.3

TABLE 66—PERCENTAGE OF PHYSICIANS PRACTICING IN GROUPS WITH 1 OR MORE ELIGIBLE PROFESSIONALS, WITH AT LEAST 20 BENEFICIARIES, CLASSIFIED BY COST—Continued

Specialty	Percentage of eligible professionals in groups (TINs) classified as		
	Low cost (percent)	Average cost (percent)	High cost (percent)
Ophthalmology	17.7	80.9	1.5
Oral surgery (dentists only)	1.5	92.4	6.1
Orthopedic surgery	3.1	91.5	5.5
Osteopathic manipulative medicine	5.7	85.8	8.5
Otolaryngology	13.4	84.3	2.3
Pain Management	1.5	86.0	12.6
Pathology	2.4	91.2	6.4
Pediatric medicine	1.2	92.6	6.2
Peripheral vascular disease	0.0	94.4	5.6
Physical medicine and rehabilitation	2.1	87.9	9.9
Plastic and Reconstructive surgery	4.2	90.4	5.4
Podiatry	2.2	91.3	6.5
Preventive medicine	3.0	91.3	5.6
Psychiatry	5.0	88.8	6.2
Pulmonary disease	3.3	92.0	4.7
Radiation oncology	4.4	83.5	12.1
Rheumatology	3.9	93.5	2.6
Single or Multispecialty clinic or group practice	5.9	85.1	9.1
Sports Medicine	2.6	94.8	2.6
Surgical oncology	1.6	82.5	16.0
Thoracic surgery	0.1	92.3	7.6
Urology	3.9	93.2	2.9
Vascular surgery	0.3	93.7	6.0

Under this methodology, we would perform this specialty adjustment prior to computing the standardized score for all six cost measures included in the value-based payment modifier: The total per capita cost measure, the four total per capita cost measures for beneficiaries with specific conditions, and the MSPB measure. The specialty adjustment for the four condition-specific total per capita cost measures is identical to the total per capita cost measure that was described above. The specialty adjustment for the MSPB cost measure is analogous to that described above for the total per capita cost measure, except that ''number of beneficiaries'' is replaced with ''number of episodes'' and ''per capita cost'' is replaced with ''per episode cost.'' Thus, each cost measure will have its own set of specialty-specific expected costs.

The second method, ''comparability peer grouping,'' constructs peer groups for each physician group practice by identifying group practices with the nearest comparable specialty mix.[8] After doing so, we would then calculate a benchmark for the peer group and then use the benchmark to calculate the group's standardized score for that measure. Under this approach, two group practices would be considered to have the same specialty mix if the share of physicians of each specialty is within a defined range for both group practices. For the purposes of computing peer groups, group practices also could be stratified by size, as measured by number of eligible professionals billing under the group practice's TIN. A group practice's peer group, however, would include a minimum number of peers (that is, group practices with similar specialty mixes) to ensure a reliable comparison. If there were fewer than the designated number of other group practices with the group practice's same specialty mix in the group practice's size category, group practices would be added to the peer group based on the next level of comparability in order to obtain the minimum number of group practices. Group practices that had a specialty mix more comparable to the practice's own mix would receive greater weight in the peer group. Among the identified peers sharing the same specialty mix, those with the most cases would receive the greatest weight.

We tested this method, based on 2011 claims, using a sample of 870 group practices of 25 or more EPs. The results showed that the comparability peer grouping approach reduced the average difference between the group's performance and benchmark rate compared to the difference between the group's performance and benchmark as computed based on the methodology we established in the CY 2013 PFS final rule with comment period and which does not consider the specialty composition of the group of physicians. Moreover, further analysis showed that this methodology consistently ranked groups of physicians. In other words, groups of physicians in the top and bottom 5th percentiles were consistent using this approach.

On balance, we believe that the first method, the specialty benchmarking method, is preferable to account for the specialty composition of the group of physicians when making peer group comparisons and creating the standardized score for the cost measures for the value-based payment modifier. We also believe this methodology allows us to apply the value-based payment modifier to smaller size groups and solo practitioners. This methodology creates one national benchmark for each cost measure. Moreover, all groups of physicians (regardless of size) are assessed against that benchmark in creating the group of physicians' standardized score. As discussed in the CY 2013 PFS final rule with comment period, we believe national benchmarks are appropriate for the value-based payment modifier (77

[8] For a description of this type of method, see, for example, Margaret M. Byrne, et al., Method to Develop Health Care Peer Groups for Quality and Financial Comparisons Across Hospitals. April 2009. HSR: Health Services Research 44:2, Part I: 577–592.

FR 69322). Although the calculations discussed above may be very detailed, they are transparent and we can provide each group of physicians with information on how its costs were benchmarked in its Quality and Resource Use Report.

By contrast, the second method, comparability peer grouping, requires us to develop a transparent way to define which groups of physicians are similar enough to be included in each group of physicians' peer group. This approach also creates a different benchmark for each group of physicians, which may make it more difficult for groups of physicians to understand how their costs are benchmarked. Notwithstanding these downsides, the comparability peer grouping method treats each group of physicians as a whole, rather than as a sum of its parts as in the specialty benchmarking method, and thus may have more acceptability among physicians. Moreover, treating the group of physicians as a whole also reinforces the shared accountability aspect of the value-based payment modifier.

Given these considerations, we propose to use the first method, the specialty benchmarking method, to create the standardized score for each group's cost measures beginning with the CY 2016 value-based payment modifier. Accordingly, we propose to amend our regulations at § 414.1255 to include this policy in our cost composite methodology. We seek comment on our proposals, including comments on ways to streamline or enhance the calculation mechanics and to make the specialty adjustments more transparent and easily understood. We also seek comment on the alternative method, the comparability peer grouping method. We propose to identify the specialty for each EP based on the specialty that is listed on the largest share of the EP's Part B claims. We understand that many physicians believe our current specialty designations may mask sub-specialist care furnished. We note that the procedures for obtaining a CMS specialty code are available at *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Taxonomy.html.*

Regardless of the method chosen, we will continue to monitor the effects of this policy over the next several years as we implement this program and may consider changes to these policies through future rulemaking.

5. Physician Feedback Program

Section 1848(n) of the Act requires us to provide confidential reports to physicians that measure the resources involved in furnishing care to Medicare FFS beneficiaries. Section 1848(n)(1)(A)(iii) of the Act also authorizes us to include information on the quality of care furnished to Medicare FFS beneficiaries. In CY 2012, we disseminated both group and individual QRURs, based on CY 2011 performance, to a wider audience than the CY 2010 reports. These reports contained improvements and enhancements suggested by the recipients of the CY 2010 reports to provide meaningful and actionable information for quality improvement. In addition, in May 2013, we provided supplemental QRURs to the group report recipients that featured episode-based costs for care of pneumonia and several acute and chronic cardiac conditions. We derived these episode-based costs using the newly developed CMS Episode Grouper software required by section 1848(n)(9)(ii) of the Act.

a. CY 2011 Physician Group Feedback Reports Based on CY 2011 Data and Disseminated in CY 2012

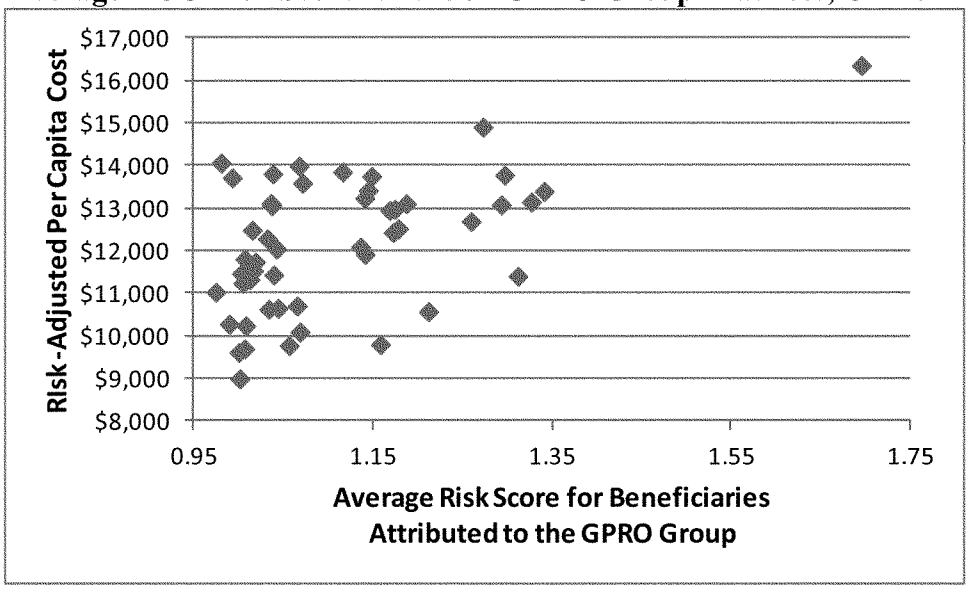
In December 2012, we produced and distributed QRURs to each of the 54 medical group practices that chose to participate in the CY 2011 GPRO under the PQRS. Each report provided information on 30 quality measures and five resource use (cost) measures for Medicare FFS beneficiaries treated by the medical groups in CY 2011. For each of the five cost measures, we standardized the input costs to adjust for differences in Medicare payments geographically and various Medicare payment policies such as Indirect Graduate Medical Education and Disproportionate Share Hospital add-on payments. We also risk adjusted the cost measures based on the unique mix of patients attributed to the physician or group of physicians. Costs for beneficiaries with high risk factors (such as a history of chronic diseases, disability, or increased age) are adjusted downward, and costs for beneficiaries with low risk factors are adjusted upward. More information on the payment standardization and risk adjustment techniques is available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/downloads/2011_group_detail_methodology.pdf.*

To participate in the PQRS GPRO in CY 2011, a group practice had to be a single provider entity, as identified by its TIN, with at least 200 eligible professionals. Fifty-four groups, encompassing 37,745 eligible professionals, participated in the 2011 PQRS GPRO. On average the group contained the following type of medical professionals: Primary care physicians (22 percent); medical specialists (22 percent); surgeons (16 percent); emergency medicine physicians (4 percent); other physicians (13 percent); and other medical professionals (23 percent).

For each of the 54 GPRO practices, we attributed a Medicare FFS beneficiary to the group if eligible professionals in the group billed for at least two of the beneficiary's eligible office visits or other outpatient evaluation and management (E&M) services provided in CY 2011 and the group practice had the plurality of CY 2011 E&M allowed charges for that beneficiary. The average beneficiary population attributed to a group practice was 12,764 beneficiaries, with the smallest group practice attributed 808 beneficiaries and the largest attributed 33,907 beneficiaries. Highlights of major findings from these 2011 QRURs are as follows:

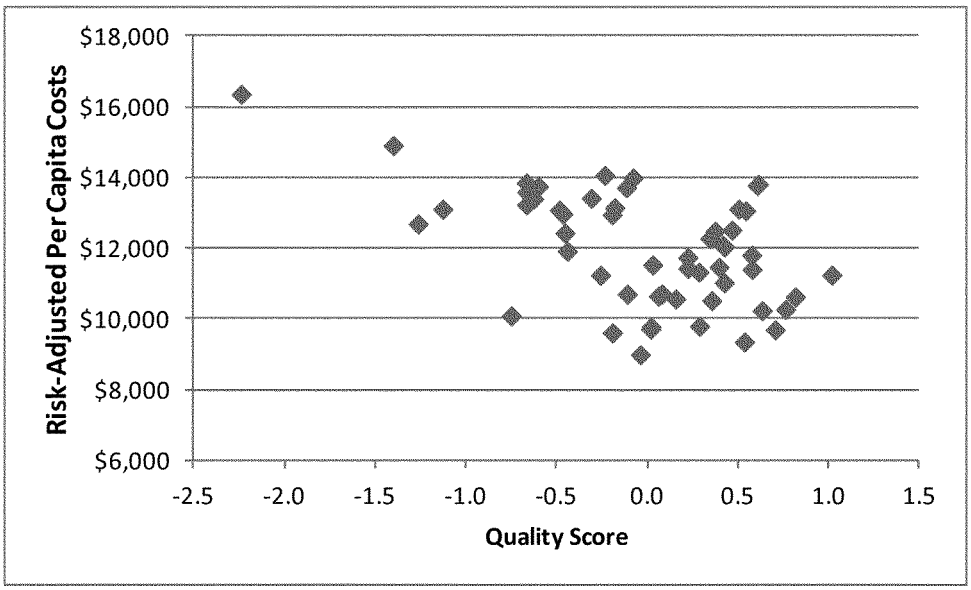
- The mean group practice performance rate on each PQRS quality measures was equal to, or better than the individual physician reported performance rate for 13 of 22 comparable quality measures (60 percent), but lower for the other 9 measures.
- Although there is a positive correlation (0.59), risk-adjusted total per capita costs for each group are fairly dispersed at any given level of risk (Table 67).

TABLE 67: Relationship Between Risk-Adjusted Total Per Capita Costs and Average HCC Risk Score for the 54 GPRO Group Practices, CY 2011



• We also constructed a quality composite score for each of the 54 groups by combining the 26 clinical quality measures, the chronic conditions ACSC composite [9] and acute conditions ACSC composite, and the two hospital discharge measures. Table 68 displays the relationship between the composite quality score for each group practice and the total payment-standardized risk-adjusted per capita cost measure. Although there is a negative correlation (−0.53), total per capita costs are fairly dispersed at any given level of quality.

TABLE 68: Quality of Care Compared to Cost, CY 2011



The performance rates for the 54 groups on the quality of care and cost measures were statistically reliable at a high level across the vast majority of the measures. More information about findings from these reports is available at *http://www.cms.hhs.gov/physicianfeedbackprogram.html.*

b. Individual Physician Feedback Reports Based on CY 2011 Data and Disseminated in CY 2012.

In December 2012, we provided individual 2011 Quality and Resource Use Reports to over 94,000 physicians

[9] The chronic conditions composite was constructed as the sum of the numerators for diabetes, COPD, and heart failure ACSC measures divided by the sum of their corresponding denominators.

affiliated with medical group practices of 25 or more eligible professionals (that is, these group practices include physicians and other medical staff such as nurse practitioners and physician assistants). The physician groups were based in 9 states: California; Illinois; Iowa; Kansas; Michigan; Minnesota; Missouri; Nebraska; and Wisconsin. Over the 4-month period during which reports were available, 31,518 individual reports were downloaded.

The QRURs contained performance on PQRS measures for physicians who participated in the CY 2011 program. They also contained performance information on 28 quality indicators for preventive care, medication management, and eight separate condition categories, such as chronic obstructive pulmonary disease (COPD) and cancer. We calculated rates for these measures using CY 2010 and CY 2011 Medicare administrative claims. Of these 28 measures, 14 measures will be included in the PQRS Administrative Claims reporting mechanism available for groups of physicians and individual EPs in CY 2013.

The QRURs also provided measures of physician resource use. These measures were payment-standardized and risk-adjusted total Parts A and B per capita costs for beneficiaries treated by the physician. Payment standardization adjusts for differences in Medicare payment rates to compare service use within or across geographic regions. Risk adjustment accounts for differences in costs among physician that result from variation in patient mix. We included five measures of cost in the QRURs: total per capita costs for all beneficiaries attributed to the physician and total per capita costs for attributed beneficiaries with one of four chronic conditions (diabetes, heart failure, COPD, or coronary artery disease (CAD)). For the cost measures, we attribute beneficiaries to physicians based on each physician's degree of involvement with the beneficiary. The three categories of attribution are directed, influenced, and contributed, which are based on the percentage of each beneficiary's evaluation and management services or total professional costs. More information about the methodologies used in the CY 2011 Individual QRURs is available at *http://www.cms.hhs.gov/physicianfeedbackprogram*.

The following is a summary of the highlights from these reports:

- Among high-risk Medicare beneficiaries, visiting a primary care physician during the year was associated with lower costs, but having a physician who is more involved in one's care (that is, the physician directed or influenced care) is associated with the lowest costs, on average. For this analysis a physician directed or influenced care if the physician billed for 35 percent or more of the patient's office or other outpatient E&M visits or for 20 percent or more of the patient's total professional costs.
- The average reliability score was high (greater than 0.70) for 98 percent (125) of the 128 PQRS measures reported by physicians in the nine states with a case size of at least 20. A total of 109 of the 128 measures (85 percent) had average reliabilities greater than 0.90. These reliability scores were substantially higher than for the 14 measures that are included in the CY 2013 PQRS Administrative Claims reporting mechanism. Reliability scores range from zero to one and measure the extent to which the performance of one physician can be confidently distinguished from another.
- The performance rate for at least 25 percent of physicians was significantly different from the mean for 5 of the 10 most reported PQRS measures in the 9 states. However, none of the 14 Administrative Claims-based measures had performance rates that were significantly different from the mean for at least 25 percent of physicians. These results suggest statistically significant variation across physicians is more likely to be detected using the most common self-reported PQRS quality measures rather than the Administrative Claims measures.
- Across the 9 states, the average of the total per capita cost (payment-standardized and risk-adjusted) among physicians was $18,735. Among total per capita costs for beneficiaries with the four chronic condition, total per capita costs for heart failure were highest ($34,545), followed by COPD ($32,946), CAD ($25,906), and diabetes ($25,016).
- Across the 9 states, the average reliability for physicians' total per capita costs was very high at 0.97, when a physician had at least 20 cases. The average reliability of the total per capita cost measure (among physicians with 20+ cases) for directed patients was 0.85, for influenced patients was 0.71, and for contributed patients was 0.97. These results demonstrate that for the typical physician profiled with a minimum case size of 20 the overall per capita cost measure is reliable.

More information about the aggregate findings from these reports is also available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ReportTemplate.html*.

c. Episode Costs and the Supplemental QRURs

Section 1848(n)(9)(A)(ii) of the Act, as added by section 3003 of the Affordable Care Act, requires CMS to develop a Medicare episode grouper by January 1, 2012, and to include episode-based costs in the QRURs. An episode of care consists of medical and/or procedural services that address a specific medical condition or procedure that are delivered to a patient within a defined time period and are captured by claims data. An episode grouper is software that organizes claims data into episodes. We have developed a CMS prototype episode grouper that, for a limited number of conditions, classifies episodes into three categories: chronic; acute; and procedural.

To illustrate how the CMS Episode Grouper works, in June 2013 we developed supplemental QRURs and made them available to the 54 large group practices that we had provided group QRURs in December 2012. The CY 2011 Supplemental Episode Grouper QRURs included the following five major episodes along with seven episode sub-types that further stratified the episode:

- Pneumonia (acute condition).
  - ++ With (inpatient) hospital stay.
  - ++ Without hospital stay.
- Acute Myocardial Infarction (AMI) (acute condition).
  - ++ Without Percutaneous Coronary Interventions (PCI) or Coronary Artery Bypass Graft (CABG).
  - ++ With PCI.
  - ++ With CABG.
- Coronary Artery Disease (CAD) (chronic condition).
  - ++ Without AMI.
  - ++ With AMI.
- CABG (without AMI) (procedural).
- PCI (without AMI) (procedural).

The Supplemental QRURs assign, or attribute, responsibility for the patient's care for each episode to a medical practice group. Episode assignment to medical practice groups for the Supplemental QRURs was based on one or more of the following three methods, depending upon the episode type:

- The performance of specific procedures.
- The plurality (35 percent) of episode EP fee schedule (PFS) costs billed.
- The plurality or shared majority (35 percent) of E&M visits.

Each of these methods relies on different criteria to attribute episodes to groups. We used the first method when a single procedure, such as a surgery, triggers, or begins, an episode of care. In this case, the group performing the

surgery is assumed to be responsible for the care. We used this method to attribute PCI and CABG episode types to group practices.

The latter two methods attribute the episode based on EPs' relative billing made during the episode. Attribution using PFS costs assumes that certain types of EPs who are paid higher amounts during the episode are likely to have interacted most with the patient and directed the patient's care. The PFS cost attribution method excludes costs from laboratories and ambulances, as well as other settings to reduce the likelihood that non-clinicians, are attributed the episode. Use of E&M visit attribution assumes that EPs who most frequently visit the beneficiary during the episode are likely to have substantial responsibility for the services rendered during the episode. The chronic CAD episode type used only E&M visits for attribution, while the acute AMI and pneumonia episodes used both PFS costs and E&M visits. More information about the group attribution methodologies is available at: *www.cms.gov/physicianfeedback program*.

To control for patient case-mix, the CMS Episode Grouper applied a risk-adjustment methodology. The risk-adjustment methodology calculated each episode's expected cost based on three factors: patient health status; demographics; and beneficiary type. Using these factors, the risk-adjustment model calculated the predicted cost of an episode using information available at the start of the episode.[10] The use of such a prospective risk model avoids allowing providers to influence their risk-adjusted costs by changing their treatment patterns during the episode. The risk-adjusted cost amount was defined to be equal to the average episode cost nationally plus the difference between the episode cost level and the predicted cost level derived from the risk-adjustment model. All cost figures used in the risk-adjustment model are payment-standardized.

To make the Supplemental QRURs more actionable for medical groups for quality improvement and care coordination, the Supplemental QRURs identify a suggested individual provider within the group who is likely to be directing the care during the episode. This individual is designated as the ''Suggested Lead Eligible Professional (EP)'' of the episode. In addition the Supplemental QRURs contained summary information about each episode type, comparisons to national benchmarks, as well as specific information describing each episode attributed to the group of physicians. More information about the Supplemental QRURs is available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html*.

We view these Supplemental QRURs as the beginning of an extended process of incorporating episode costs into the QRURs. We intend to develop the CMS Episode Grouper (based in the CMS' Center for Medicare and Medicaid Innovation) and to broaden the number of conditions that could be addressed by episode grouping. The feedback that CMS expects from the 54 medical practice groups report recipients will inform next steps.

d. Future Plans for the Physician Feedback Reports

In September, 2013, we plan to provide the QRURs at the TIN level to all groups of physicians with 25 or more eligible professionals. The QRURs will be based on CY 2012 performance data. We anticipate that there will be approximately 6,750 reports (including 1,235 groups of 100 or more EPs) covering approximately 440,000 physicians. These reports will include a ''first look'' at the value-based payment modifier methodologies using the group's PQRS measures, outcome measures, and cost measures.

The reports also incorporate many valuable suggestions we have received from specialty societies and professional societies on ways to make these reports more meaningful and actionable. In particular, the reports will contain details regarding: (1) Beneficiaries attributed to the group practice (for example, beneficiary identifying information, information regarding services furnished by the group to the beneficiary, risk score percentile, last hospital admission, and chronic conditions); (2) Physicians and non-physician eligible professionals billing under the group's TIN; and (3) Hospitalizations for attributed beneficiaries to help each group manage its patients and potentially reduce hospital admissions (including, for example, (a) beneficiary identifying information, (b) hospital admission data such as data of admission, admitting hospital, principal diagnosis, and (c) discharge disposition information). We plan to provide this additional information to support the group's quality improvement and care coordination efforts. As part of its review of these detailed reports, each group will also be able to compare the data in the reports with its own records (for example, professionals billing under the group's TIN) to verify the information in the CMS reports. We note that these reports are developed following a 90-day claim run-out, meaning that claims for services furnished during CY 2012 are included in the reports if the claim was paid by March 31, 2013.

We will continue to develop and refine the annual QRURs in an iterative manner. As we have done in previous years, we will seek to further improve the reports by welcoming suggestions from recipients, specialty societies, professional associations, and others. We have worked with several specialty societies representing physicians in anesthesiology, cardiology, cardiothoracic surgery, emergency medicine, neurosurgery, pathology, and radiology to develop episode costs or other cost or utilization metrics to include in the annual QRURs. We believe these efforts could be productive as we use the QRURs to not only describe how the value-based payment modifier would apply to the group of physicians, but to provide these groups with utilization and other statistics that can be used for quality improvement and care coordination.

In the late summer of 2014, we plan to disseminate the QRURs based on CY 2013 data to all physicians (that is, TINs of any size) even though groups of physicians with fewer than 100 eligible professionals will not be subject to the value-based payment modifier in CY 2015. These reports will contain performance on the quality and cost measures used to score the composites and additional information to help physicians coordinate care and improve the quality of care furnished.

We continue to look at ways to streamline the QRURs supporting the PQRS and the physician value-based payment modifier programs in order to create one unified format for quality assessment to increase their utility in future years.

L. Updating Existing Standards for E-Prescribing Under Medicare Part D

1. Background

a. Legislative History

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended title XVIII of the Act to establish a voluntary prescription drug benefit program at section 1860D–4(e) of the Act. Among other things,

[10] CAD episodes are risk-adjusted each quarter, and the data used for risk adjustment is updated with each new quarter.

these provisions required the adoption of Part D e-prescribing standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

For a further discussion of the statutory basis for this proposed rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. (Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256).

b. Regulatory History

(1) Foundation and Final Standards

CMS utilized several rounds of rulemaking to adopt standards for the e-prescribing program. Its first rule, which was published on November 7, 2005 (70 FR 67568), adopted three standards that were collectively referred to as the ''foundation'' standards. We issued a subsequent rule on April 7, 2008 (73 FR 18918) that adopted additional standards which are referred to as ''final'' standards. One of these standards, the NCPDP Formulary and Benefit Standard, Implementation Guide, Version 1, Release 0 (Version 1.0, hereafter referred to as the NCPDP Formulary and Benefit 1.0) was a subject of the calendar year (CY) 2013 Physician Fee Schedule (PFS) final rule with comment period (77 FR 68892 at 69329) and is the subject of this proposed rule. Please see the ''Initial Standards Versus Final Standards'' discussion at 70 FR 67568 in the November 7, 2005 rule for a more detailed discussion about ''foundation'' and ''final'' standards.

(2) Updating e-Prescribing Standards

As noted previously, transaction standards are periodically updated to take new knowledge, technology and other considerations into account. As CMS adopted specific versions of the standards when it adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could be updated or replaced over time to ensure that the standards did not hold back progress in the industry. CMS discussed these processes in its November 7, 2005 final rule (70 FR 67579).

The discussion noted that the rulemaking process will generally be used to retire, replace or adopt a new e-prescribing standard, but it also provided for a simplified ''updating process'' when a standard could be updated with a newer ''backward-compatible'' version of the adopted standard. In instances in which the user of the later version can accommodate users of the earlier version of the adopted standard without modification, it noted that notice and comment rulemaking could be waived, in which case the use of either the new or old version of the adopted standard would be considered compliant upon the effective date of the newer version's incorporation by reference in the **Federal Register**.

(3) The NCPDP Formulary and Benefit Standard in the Part D e-Prescribing Regulations

The backward compatibility concept has been used extensively to update the NCPDP SCRIPT standard in the Part D e-prescribing program, but it has not yet been used to update the adopted NCPDP Formulary and Benefit Standard. We proposed to update the NCPDP Formulary and Benefit 1.0 standard for the first time in the CY 2013 PFS proposed rule (77 FR 44722), but we did not ultimately finalize those proposals. Specifically, we proposed to recognize NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of NCPDP Formulary and Benefits 1.0 effective 60 days from the publication of the final rule, and sought comment on when we should retire NCPDP Formulary and Benefits 1.0 as well as when we should adopt NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard. As was noted in that rule, while recognition of backward compatible versions can be done in an interim final rule in which we waive notice and comment rulemaking, other Part D e-prescribing proposals that were being made at that time required full notice and comment rulemaking, so, as we didn't wish to publish two e-prescribing rules contemporaneously, we elected to forgo our usual use of our simplified updating process for backward compatible standards (in which we waive notice and comment rulemaking and go straight to final) in favor of putting all of the proposals through full notice and comment rulemaking.

2. Proposals

a. Proposed Backward Compatible Standards

As was discussed in the CY 2013 PFS final rule with comment period (77 FR 68892), we were persuaded by commenters to refrain from retiring Formulary and Benefit Standard 1.0 until NCPDP ceased supporting it on July 1, 2014. As further noted in that rule, we believed it best to delay implementing any of our Formulary and Benefits proposals, including recognitions of NCPDP Formulary and Benefit 3.0 as a backward compatible standard, until closer to that July 1, 2014 date. Our actions at that time were based on a belief that an extended period of use of either 3.0 or 1.0 would be ill-advised.

Having come within roughly a year of the anticipated date upon which NCPDP will cease supporting NCPDP Formulary and Benefit 1.0, we believe that it is now appropriate to re-propose the recognition of NCPDP Formulary and Benefits 3.0 as a backward compatible version of Formulary and Benefits 1.0 effective 60 days after publication of a final rule until June 30, 2014, and, as discussed below, to propose the retirement of NCPDP Formulary and Benefits 1.0, effective July 1, 2014, and to propose the adoption of NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard effective July 1, 2014. As was discussed previously, while the recognition of backward compatible standards can be done in an interim final rule in which we waive notice and comment rulemaking, in light of other Part D e-prescribing proposals being made in this rule that require full notice and comment rulemaking, we will forgo use of the simplified updating method for backward compatible standards (in which we waive notice and comment rulemaking and go straight to final) in favor of putting all of the proposals through a single notice and comment rulemaking.

Also, as was seen in our prior proposal to recognize backward compatibility using full notice and comment in place of the backward compatible methodology, we must also propose to require users of 3.0 to support users who are still using NCPDP Formulary and Benefit 1.0 until such time as that version is officially retired as a Part D e-prescribing standard and NCPDP Formulary and Benefit 3.0 is adopted as the official Part D e-prescribing standard.

2. Proposed Retirement of NCPDP Formulary and Benefit Standard 1.0 and adoption of NCPDP Formulary and Benefit Standard 3.0

As noted in the CY 2013 PFS proposed rule, the NCPDP Formulary and Benefits standard provides a uniform means for pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via point-of-care (POC) systems. These include:

- General formulary data (for example, therapeutic classes and subclasses);
- Formulary status of individual drugs (that is, which drugs are covered);
- Preferred alternatives (including any coverage restrictions, such as quantity limits and need for prior authorization); and
- Copayment (the copayments for one drug option versus another).

Also as noted in that proposed rule, standards are updated over time to take industry feedback and new and modified business needs into account. See the CY 2013 PFS proposed rule (77 FR 45023–45024) for a full discussion of the changes to that were made to the NCPDP Formulary and Benefit 1.0 as it was updated to the NCPDP Formulary and Benefit 3.0.

As noted above, having come within roughly a year of the anticipated date upon which NCPDP will cease supporting NCPDP Formulary and Benefit 1.0, we believe that it is now appropriate to re-propose the retirement of NCPDP Formulary and Benefits 1.0, effective July 1, 2014, and to propose the adoption of NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard, effective July 1, 2014.

To effectuate these proposals, we propose to revise § 423.160(b)(5). We propose to place the existing material in a new paragraph (b)(5)(i), which would provide the formulary and benefit standard for Part D e-prescribing until [60 days after publication of the final rule]. We then propose to create a second new paragraph ((b)(5)(ii)) to recognize NCPDP Formulary and Benefit 3.0. as a backward compatible version of the official Part D e-prescribing standard (NCPDP Formulary and Benefit 1.0), effective [60 days after publication of the final rule] through June 30, 2014. Furthermore, we propose to create a third new paragraph ((b)(5)(iii)) to reflect the retirement of NCPDP Formulary and Benefit 1.0 and the adoption of NCPDP Formulary and Benefit 3.0 as the official Part D e-prescribing standard, effective July 1, 2014. Finally, we propose to make conforming changes to § 423.160(b)(1). We seek comment on these proposals.

M. Discussion of Budget Neutrality for the Chiropractic Services Demonstration

Section 651 of MMA requires the Secretary to conduct a demonstration for up to 2 years to evaluate the feasibility and advisability of expanding coverage for chiropractic services under Medicare. Current Medicare coverage for chiropractic services is limited to treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act provided such treatment is legal in the state or jurisdiction where performed. The demonstration expanded Medicare coverage to include: ''(A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; and (B) diagnostic and other services that a chiropractor is legally authorized to perform by the state or jurisdiction in which such treatment is provided.'' The demonstration was conducted in four geographically diverse sites, two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). The two urban sites were 26 counties in Illinois and Scott County, Iowa, and 17 counties in Virginia. The two rural sites were the States of Maine and New Mexico. The demonstration, which ended on March 31, 2007, was required to be budget neutral as section 651(f)(1)(B) of MMA mandates the Secretary to ensure that ''the aggregate payments made by the Secretary under the Medicare program do not exceed the amount which the Secretary would have paid under the Medicare program if the demonstration projects under this section were not implemented.''

In the CY 2006, 2007, and 2008 PFS final rules with comment period (70 FR 70266, 71 FR 69707, 72 FR 66325, respectively), we included a discussion of the strategy that would be used to assess budget neutrality (BN) and the method for adjusting chiropractor fees in the event the demonstration resulted in costs higher than those that would occur in the absence of the demonstration. We stated that BN would be assessed by determining the change in costs based on a pre-post comparison of total Medicare costs for beneficiaries in the demonstration and their counterparts in the control groups and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We also stated that our analysis would not be limited to only review of chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs for other services.

In the CY 2010 PFS final rule with comment period (74 FR 61926), we discussed the evaluation of this demonstration conducted by Brandeis University and the two sets of analyses used to evaluate BN. In the ''All Neuromusculoskeletal Analysis,'' which compared the total Medicare costs of all beneficiaries who received services for a neuromusculoskeletal condition in the demonstration areas with those of beneficiaries with similar characteristics from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was $114 million higher costs for beneficiaries in areas that participated in the demonstration. In the ''Chiropractic User Analysis,'' which compared the Medicare costs of beneficiaries who used expanded chiropractic services to treat a neuromusculoskeletal condition in the demonstration areas, with those of beneficiaries with similar characteristics who used chiropractic services as was currently covered by Medicare to treat a neuromusculoskeletal condition from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was a $50 million increase in costs.

As explained in the CY 2010 PFS final rule, we based the BN estimate on the ''Chiropractic User Analysis'' because of its focus on users of chiropractic services rather than all Medicare beneficiaries with neuromusculoskeletal conditions, as the latter included those who did not use chiropractic services and who may not have become users of chiropractic services even with expanded coverage for them (74 FR 61926 through 61927). Users of chiropractic services are most likely to have been affected by the expanded coverage provided by this demonstration. Cost increases and offsets, such as reductions in hospitalizations or other types of ambulatory care, are more likely to be observed in this group.

As explained in the CY 2010 PFS final rule (74 FR 61927), because the costs of this demonstration were higher than expected and we did not anticipate a reduction to the PFS of greater than 2 percent per year, we finalized a policy to recoup $50 million in expenditures from this demonstration over a 5-year period, from CYs 2010 through 2014 (74 FR 61927). Specifically, we are recouping $10 million for each such year through adjustments to the

chiropractic CPT codes. Payment under the PFS for these codes will be reduced by approximately 2 percent. We believe that spreading this adjustment over a longer period of time will minimize its potential negative impact on chiropractic practices.

For the CY 2013 PFS, our Office of the Actuary (OACT) estimated chiropractic expenditures to be approximately $470 million, which reflected the statutory 26.5 percent reduction to PFS payments scheduled to take effect that year. The statute was subsequently amended to impose a zero percent PFS update for CY 2013 instead of the 26.5 percent reduction. In large part because of the change in the PFS update, OACT now estimates CY 2013 chiropractic expenditures to be approximately $580 million. Because of the change in projected chiropractic expenditures, we now expect to recoup approximately $11.6 million from the 2 percent payment reduction for chiropractic CPT codes in CY 2013.

We expect to complete the required BN adjustment by recouping the remainder of the chiropractic expenditures in CY 2014. For each year of this recoupment, we have provided OACT's projected chiropractic expenditures based on previous year's data. While OACT's projections have included the statutory reductions to physician payments, the statute was amended in each year to avoid these reductions. As a result, Medicare expenditures for chiropractic services during the recoupment were higher than the OACT projections. Chiropractic services expenditures during the recoupment period have been as follows: $540 million in 2010; $520 million in 2011; and $580 million in 2012. In total, CMS recouped $32.8 million over the years of 2010, 2011 and 2012. OACT now projects chiropractic expenditures to be approximately $580 million in 2013. A 2 percent recoupment percentage for chiropractic services would result in approximately $11.6 million in 2013. For the years 2010 through 2013, CMS would have recouped approximately $44.4 million of the $50 million required for budget neutrality.

In 2014, CMS is reducing the recoupment percentage for the chiropractic codes to ensure the recoupment does not exceed the $50 million required for budget neutrality. OACT estimates chiropractic expenditures in CY 2014 will be approximately $480 million based on Medicare spending for chiropractic services for the most recent available year and reflecting an approximate 25 percent reduction to physician payments scheduled to take effect under current law. CMS plans to recoup the remaining funds, approximately $5.6 million, and will reduce chiropractic CPT codes (CPT codes 98940, 98941, and 98942) by the appropriate percentage, which by our preliminary estimates is one percent which takes into account the approximately 25 percent reduction in physician payments scheduled to occur in 2014 as provided under current law. If the statute is amended to avoid the physician payment reduction, we will reduce the recoupment percentage as appropriate to ensure the recoupment does not exceed $50 million. For instance, if the statute is amended to provide for a zero percent PFS update, we would reduce the recoupment percentage to approximately 0.7 percent. We will reflect this reduction only in the payment files used by the Medicare contractors to process Medicare claims rather than through adjusting the RVUs. Avoiding an adjustment to the RVUs preserves the integrity of the PFS, particularly since many private payers also base payment on the RVUs.

Therefore, as finalized in the CY 2010 PFS regulation and reiterated in the CYs 2011 through 2013 PFS regulations, we are implementing this methodology and recouping excess expenditures under the chiropractic services demonstration from PFS payment for the chiropractor codes as set forth above. This recoupment addresses the statutory requirement for BN and appropriately impacts the chiropractic profession that is directly affected by the demonstration. We intend for CY 2014 to be the last year of this required recoupment.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

1. ICRs Regarding Medical Services Coverage Decisions That Relate to Health Care Technology (§ 405.211)

The burden associated with the requirements under § 405.211 is the time and effort it would take a study sponsor that is requesting Medicare coverage of an FDA-approved IDE to prepare the following as electronic documents: (1) A copy of the FDA IDE approval letter; (2) a copy of the IDE study protocol; (3) a copy of IRB approval letter(s); and (4) the *ClinicalTrails.gov* identifier. CMS reviews these documents to determine whether it should cover certain costs in an IDE trial or study.

Each IDE trial sponsor will have to prepare these documents once. If the sponsor requests a second review, the documents will have to be sent again. We estimate that this may happen 5–8 percent of the time. Since the IDE rule was passed in September 1995 through 2012, there have been 4,000 IDE applications, averaging 222 per year. Adding another 8 percent brings the total estimate of about 240 requests per year.

The study sponsors do not have to create new documents. Rather they will be required to send us copies of information they have sent to the FDA and that the FDA has sent to them. Accordingly, we estimate that it will take 1 hour for an executive administrative assistant in a medical device company to prepare: (1) A copy of the FDA IDE approval letter; (2) a copy of the IDE study protocol; (3) a copy of IRB approval letter(s); and (4) the ClinicalTrails.gov identifier, for electronic submission.

We estimate that for 240 requests per year, that the total estimated cost to the public is $7,821 annually. In deriving these figures, we used the Bureau of Labor Statistics May 2012 estimate of $24.14 + 35 percent in fringe benefits for estimated hourly wage of $32.59 for an executive administrative assistant (occupation code 43–6011).

2. ICRs Regarding the Physician Quality Reporting System (PQRS) (§ 414.90)

We are making certain revisions to § 414.90, primarily to include our proposals for the qualified clinical data registry option. All of the requirements

and burden estimates are currently approved by OMB under OCN 0938–1059, and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

We are revising § 414.90(b), (c), and (e) to indicate our proposals for the qualified clinical data registry option. While the sections contain information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions.

The preamble of this proposed rule discusses the background of the PQRS, provides information about the measures and reporting mechanisms that would be available to eligible professionals and group practices who choose to participate in 2014, and provides the proposed criteria for satisfactory reporting in 2014 (for the 2014 PQRS incentive and the 2016 PQRS payment adjustment). Below are our burden estimates for participating in the PQRS in 2014 which are subject to OMB review/approval under OCN 0938–1059.

a. Participation in the 2013 and 2014 PQRS

In the CY 2013 PFS final rule with comment period, we provided estimates related to the impact of the requirements we finalized for the PQRS for 2014. Since we are proposing additional proposals, this section modifies the impact statement provided in the CY 2013 PFS final rule with comment period for reporting in 2014. Please note that we will base our estimates on information found in the 2011 Physician Quality Reporting System and eRx Reporting Experience and Trends (hereinafter ''the PQRS Reporting Experience''). This report contains the latest data we have gathered on PQRS participation. The PQRS Reporting Experience is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/*. According to the 2011 Reporting Experience Report, over 1 million professionals were eligible to participate in the PQRS. A total of $261,733,236 in PQRS incentives was paid by CMS for the 2011 program year, which encompassed 26,515 practices that included 266,521 eligible professionals (or approximately 27% of the professionals eligible to participate). The average incentive earned for PQRS in 2011 per each individually-participating eligible professional was $1,059.

As we noted in our impact statement last year, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the PQRS would rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively. We believe our estimate of 400,000 eligible professionals participating in PQRS in 2014 is accurate.

With respect to the estimated amount of incentives earned, for 2014, eligible professionals can earn a 0.5 percent incentive (i.e., a bonus payment equal to 0.5 percent of the total allowed part B charges for covered professional services under the PFS furnished by the eligible professional during the reporting period) for satisfactory reporting, a reduction of 1.0 percent from 2011. Based on information drawn from the 2011 Reporting Experience and our participation estimate, we believe that, out of the 400,000 eligible professionals we expect to participate in the PQRS in 2014, the PQRS will distribute 2014 incentives to approximately (27% of 1 million eligible professionals) 270,000 eligible professionals. At $1,059 per eligible professional, the PQRS would distribute approximately $286 million in incentive payments in 2014. We believe these incentive payments will help offset the cost eligible professionals may undertake for participating in the PQRS for the applicable year.

We note that the total burden associated with participating in the PQRS is the time and effort associated with indicating intent to participate in the PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assume the following:

- The proposals for reporting for the PQRS for the 2014 incentive and 2016 payment adjustment would be established as proposed in this CY 2014 Medicare PFS proposed rule.
- For an eligible professional or group practice using the claims, qualified registry, qualified clinical data registry, or EHR-based reporting mechanisms, we assume that the eligible professional or group practice would attempt to report PQRS quality measures data with the intention of earning the 2014 PQRS incentive. Therefore, an eligible professional or group practice would report on 9 measures.
- With respect to labor costs, we believe that a billing clerk will handle the administrative duties associated with participating, while a computer analyst will handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately $16/hour whereas the mean hourly wage for a computer analyst is approximately $40/hour.

Please note that these estimates do not reflect total costs estimates for participating in PQRS, but rather cost estimates that would change if our proposals are finalized.

b. Burden Estimate on Participation in the CYs 2013 and 2014 PQRS—New Individual Eligible Professionals: Preparation

For an eligible professional who wishes to participate in PQRS as an individual, the eligible professional need not indicate his/her intent to participate. Instead, the eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in PQRS are based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice would spend 5 hours—which includes 2 hours to review PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in PQRS would be approximately $80 ($16/hour × 5 hours).

c. Burden Estimate on Participation in the 2013 and 2014 PQRS via the Claims-Based Reporting Mechanism—Individual Eligible Professionals

Historically, the claims-based reporting mechanism is the most widely used reporting mechanism in PQRS. In 2011, 229,282 of the 320,422 eligible professionals (or 72 percent of eligible professionals) used the claims-based reporting mechanism. In the CY 2013 PFS final rule with comment period, we estimated that approximately 320,000 eligible professionals, whether participating individually or in a group practice, would participate in PQRS by CY 2014 (77 FR 69338). We believe this estimate should be further modified to reflect a lower participation estimate in 2014 due to the following proposals:

- We are proposing to eliminate the option to report measures groups via claims for the 2014 PQRS incentive.

• We are proposing to increase the number of measures that an eligible professional must report to meet the criteria for satisfactory reporting for the 2014 PQRS incentive from 3 measures to 9, but lower the reporting threshold to 50%.

• We are proposing to remove the claims-based reporting mechanism as an option for reporting certain individual quality measures.

Based on these proposals, we estimate that approximately 230,000 eligible professionals (that is, the same number of eligible professionals who participated in the PQRS using the claims-based reporting mechanism in 2011) will participate in the PQRS using the claims-based reporting mechanism. Therefore, we estimate that approximately 58 percent of the eligible professionals participating in PQRS will use the claims-based reporting mechanism.

With respect to an eligible professional who participated in PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submitted for payment. PQRS will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN 0938–0999). Based on our experience with Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims would range from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 9 measures would range from 2.25 minutes to 108 minutes. Using an average labor cost of $40/hour, we estimated that the time cost of reporting for an eligible professional via claims would range from $1.50 (2.25 minutes or 0.0375 hours × $40/hour) to $72.00 (108 minutes or 1.8 hours × $40/hour) per reported case. With respect to how many cases an eligible professional would report when using the claims-based reporting mechanism, we established that an eligible professional would need to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which eligible professional reports would vary depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent for claims-based reporting, we found that the median number of reporting cases for each measure was 9. Since we reduced the reporting threshold to 50 percent, we estimated that the average number of reporting cases for each measure would be reduced to 6. Based on these estimates, we estimated that the total cost of reporting for an eligible professional choosing the claims-based reporting mechanism would range from ($1.50/per reported case × 6 reported cases) $9.00 to ($72.00/reported case × 6 reported cases) $432.

d. Burden Estimate on PQRS Participation in CY 2014 via the Qualified Registry, Qualified Clinical Data Registry, or EHR Reporting Mechanisms

We noted previously that we estimate a significant reduction in the number of eligible professionals using the claims-based reporting mechanism to report PQRS quality measures data in 2014. Specifically, we estimate that approximately 230,000 eligible professionals will participate in the PQRS using the claims-based reporting mechanism in 2014. Therefore, we estimate that the remainder of the eligible professionals (170,000) will participate in PQRS using either the qualified registry, qualified clinical data registry, EHR (using either a direct EHR or EHR data submission vendor), or the GPRO web interface reporting mechanisms.

With respect to participation in a qualified registry or qualified clinical data registry, we are combining our estimates for the number of eligible professionals we believe will use the qualified registry and qualified clinical data registry reporting mechanisms for the 2014 PQRS incentive and 2016 PQRS payment adjustment. We are combining these estimates because we believe that, at least for this initial year, many of the registries that become qualified clinical data registries will also be existing qualified registries. As such, we anticipate there will be little to no additional registries that will submit quality measures data to the PQRS for purposes of the 2014 PQRS incentive and 2016 PQRS payment adjustment.

In 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the registry-based reporting mechanism. We believe the number of eligible professionals and group practices using a qualified registry or qualified clinical data registry would remain the same, as eligible professionals use registries for functions other than PQRS and therefore would obtain a qualified registry or qualified clinical data registry solely for PQRS reporting by CY 2014. Please note that this estimate would include participants choosing the newly proposed qualified clinical data registry reporting mechanism. At least in its initial stage, we believe most of the vendors that would be approved to be a qualified clinical data registry would be existing qualified registries.

In 2011, 560 (or less than 1%) of the 320,422 eligible professionals participating in PQRS used the EHR-based reporting mechanism. We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism would increase as eligible professionals become more familiar with EHR products and more eligible professionals participate in programs encouraging use of an EHR, such as the EHR Incentive Program. In particular, we believe eligible professionals and group practices would transition from using the claims-based to the EHR-based reporting mechanisms. We estimate that approximately 50,000 eligible professionals (which is the same estimate as we are providing for eligible professionals who use the qualified registry or qualified clinical data registry-based reporting mechanisms), whether participating as an individual or part of a group practice, would use the EHR-based reporting mechanism in CY 2014.

With respect to an eligible professional or group practice who participated in PQRS via a qualified registry, qualified clinical data registry, direct EHR product, or EHR data submission vendor's product, we believe there would be little to no burden associated for an eligible professional to report PQRS quality measures data to CMS, because the selected reporting mechanism submitted the quality measures data for the eligible professional. While we noted that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, or EHR data submission vendor, we believe that an eligible professional or group practice would not purchase a qualified registry, qualified clinical data registry, direct EHR product, or EHR data submission vendor product solely for the purpose of reporting PQRS quality measures. Therefore, we have not included the cost of purchasing a qualified registry, direct EHR, or EHR data submission vendor product in our burden estimates.

e. Burden Estimate on PQRS Participation in CY 2014—Group Practices

Please note that with the exception of the estimates associated with a group self-nominating to participate in the PQRS under the GPRO, this section only contains our estimates for group

practices who participate in the PQRS under the GPRO via the GPRO web interface reporting mechanism. We note that the burden associated with reporting quality measures for group practices using the qualified registry or EHR-based reporting mechanisms are included in the estimates we provided for the qualified registry or EHR-based reporting mechanisms above. According to the PQRS and eRx Experience report, of the 101 practices participating in the GPRO, 54 of these practices participated using the GPRO web interface (formerly the GPRO tool). We estimate that because we are proposing to apply the value-based payment modifier to all group practices of 10 or more eligible professionals, we estimate that approximately 30% of such group practices, or about 5,100 group practices, will participate in the PQRS under the GPRO for purposes of the 2014 PQRS incentive and the 2016 payment adjustment. In addition, we estimate that of the 5,100 group practices that are expected to self-nominate to participate in the PQRS under the GPRO, approximately 70,000 eligible professionals (i.e. the remainder of the eligible professionals not participating in PQRS using the claims, qualified registry, qualified clinical data registry, or EHR-based reporting mechanisms), representing about 30% of the groups with 100 or more eligible professionals (or about 340 groups), will choose to participate in PQRS using the GPRO web interface for purposes of the 2014 PQRS incentive and the 2016 PQRS payment adjustment.

Unlike eligible professionals who choose to report individually, we noted that we proposed that eligible professionals choosing to participate as part of a group practice under the GPRO would need to indicate their intent to participate in PQRS as a GPRO. The total burden for group practices who submit PQRS quality measures data via the GPRO web-interface would be the time and effort associated with submitting this data. To submit quality measures data for PQRS, a group practice would need to (1) be selected to participate in the PQRS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in PQRS as a GPRO, we believe it would take approximately 6 hours—including 2 hours to decide to participate in PQRS as a GPRO; 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials—for a group practice to be selected to participate in PQRS GPRO for the applicable year. Therefore, we estimate that the cost of undergoing the GPRO selection process would be ($16/hour × 6 hours) $96.

With respect to reporting PQRS quality measures using the GPRO web-interface, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimate the burden associated with a group practice completing the data collection interface would be approximately 79 hours. Therefore, we estimate that the report cost for a group practice to submit PQRS quality measures data for an applicable year would be ($40/hour × 79 hours) $3,160.

In addition to the GPRO web interface, please note that we have proposed a new reporting mechanism that would be available to group practices comprised of 25+ eligible professionals: the certified survey vendor. With respect to using a certified survey vendor, we believe there would be little to no burden associated for a group practice to report the CG CAHPS survey data to CMS, because the selected reporting mechanism submitted the quality measures data for the group practice. While there may be start-up costs associated with purchasing a certified survey vendor, we believe that a group practice would not purchase a certified survey vendor solely for the purpose of reporting the CG CAHPS survey for the PQRS. Therefore, we have not included the cost of purchasing a certified survey vendor in our burden estimates.

f. Burden Estimate on PQRS Vendor Participation in CY 2014

Aside from the burden of eligible professionals and group practices participating in PQRS, we believe that entities that wish to become qualified clinical data registries would incur costs associated with participating in PQRS. However, we believe that the burden associated with participating in PQRS for these entities would be very similar to the burden associated with existing qualified registries participating in PQRS.

Based on the number of registries that have self-nominated to become a qualified PQRS registry in prior program years, we estimated that approximately 50 additional registries would self-nominate to be considered a qualified registry for PQRS. With respect to qualified registries and qualified clinical data registries, the total burden for qualified registries and qualified clinical data registries who submitted PQRS quality measures data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed PQRS program years, a registry would need to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process, we estimated that it would take a total of 10 hours—including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wished to report using a CMS-provided measure flow, and 5 hours to complete an XML submission—to become qualified to report PQRS quality measures data. Therefore, we estimate that it would cost a registry approximately ($16.00/hour × 10 hours) $160 to become qualified to submit PQRS quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, the burden associated with reporting is the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. We believe, however, that registries already perform these functions for its eligible professionals irrespective of participating in PQRS. Therefore, we believe there is little to no additional burden associated with reporting PQRS quality measures data. Whether there is any additional reporting burden would vary with each registry, depending on the registry's level of savvy with submitting quality measures data for PQRS.

For CY 2014, we are proposing a new PQRS option that includes a new reporting mechanism—the qualified clinical data registry. In this proposed rule, we set forth the requirements for a vendor to become qualified to become a qualified clinical data registry. Under the proposed requirements, we note that a vendor can be both a traditional qualified registry and qualified clinical data registry under the PQRS. Indeed, as we noted previously, we believe that many of the entities that will seek to become qualified clinical data registries will be similar to the existing qualified registries. In addition, at least initially, we propose that the process for becoming a qualified clinical data registry would be similar to the process for becoming a qualified registry. Therefore, we do not believe this new

reporting mechanism will impact our registry estimates.

h. Summary of Burden Estimates on Participation in the 2013 and 2014 PQRS—Eligible Professionals and Vendors

TABLE 69—ESTIMATED COSTS FOR REPORTING PQRS QUALITY MEASURES DATA FOR ELIGIBLE PROFESSIONALS

	Hours	Cases	Number of measures	Hourly rate	Cost per respondent	Number of respondents	Total cost
Individual Eligible Professional (EP): Preparation	5.0	1	N/A	$16	$80	320,422	$32,000,000
Individual EP: Claims	0.2	6	3	$40	$144	230,000	$33,120,000
Individual EP: Registry	N/A	1	N/A	N/A	Minimal	40,422	[1] N/A
Individual EP: EHR	N/A	1	N/A	N/A	Minimal	50,000	[1] N/A
Group Practice: Self-Nomination	6.0	1	N/A	$16	$96	5,100	$489,600
Group Practice: Reporting	79	1	N/A	$40	$3,160	340	$1,074,400

[1] We believe that eligible professionals who choose to report quality measures data to PQRS using a registry, an EHR, or an EHR data submission vendor are already doing so for other purposes. Therefore, there would be little to no burden associated with reporting the quality data to CMS under PQRS.

TABLE 70—ESTIMATED COSTS TO REGISTRIES TO PARTICIPATE IN PQRS

	Hours	Hourly rate	Cost	Number of respondents	Total cost
Registry: Self-Nomination	10	$16	$160	50	$8,000

3. The Medicare EHR Incentive Program

The Medicare EHR Incentive Program provides incentive payments to eligible professionals, eligible hospitals, and CAHs that demonstrate meaningful use of certified EHR technology. We believe any burden or impact associated with our proposals regarding the EHR Incentive Program is already absorbed by the currently approved (OCN 0938–1158) burden and impact estimates provided the EHR Incentive Program. Consequently, the proposed requirements (and burden) are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

4. Submission of PRA-Related Comments

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–1590–FC]

Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We considered all comments we received by the date and time specified in the **DATES** section of this preamble, and, when we proceeded with a subsequent document, we responded to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Affordable Care Act (Pub. L. 111–148), the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96), the American Taxpayer Relief Act (ATRA) of 2013 (Pub. L. 112–240), and other statutory changes. This proposed rule also is necessary to make changes to other Part B related policies.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed below in this section, that the PFS provisions included in this proposed rule will redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 million in any 1 year (for details see the SBA's Web site at *http://www.sba.gov/content/small-business-size-standards#* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

For purposes of the RFA, physicians, NPPs, and suppliers are considered small businesses if they generate revenues of $10 million or less based on SBA size standards. Approximately 95 percent of providers and suppliers are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section as well as elsewhere in this proposed rule is intended to comply with the RFA requirements.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This proposed rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

We have prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we are proposing to implement a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and Malpractice RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2013 with proposed payment rates for CY 2014 using CY 2012 Medicare utilization as the basis for the comparison. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician could vary from the average and would depend on the mix of services the physician furnishes. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

We note that these impacts do not include the effect of the January 2014 conversion factor changes under current law. The annual update to the PFS conversion factor is calculated based on a statutory formula that measures actual versus allowed or ''target'' expenditures, and applies a sustainable growth rate (SGR) calculation intended to control growth in aggregate Medicare expenditures for physicians' services. This update methodology is typically referred to as the ''SGR'' methodology, although the SGR is only one component of the formula. Medicare PFS payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted to eventually bring actual expenditures back in line with targets. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased. By law, we are required to apply these updates in accordance with sections 1848(d) and (f) of the Act, and any negative updates can only be averted by an Act of the Congress. While the Congress has provided temporary relief from negative updates for every year since 2003, a long-term solution is critical. We are committed to working with the Congress to reform Medicare physician payments to provide predictable payments that incentivize quality and efficiency in a fiscally responsible way. We provide our most recent estimate of the SGR and physician update for CY 2014 on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/index.html?redirect=/SustainableGRatesConFact/*.

Tables 71 and 72 show the payment impact on PFS services. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different from those shown in Tables 71 (CY 2014 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty) and 72 (CY 2014 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty by Selected Proposal).

The following is an explanation of the information represented in Table 71:

- *Column A (Specialty):* The Medicare specialty code as reflected in our physician/supplier enrollment files.

• *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2012 utilization and CY 2013 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.

• *Column C (Impact of Work and Malpractice (MP) RVU Changes):* This column shows the estimated CY 2014 impact on total allowed charges of the changes in the work and malpractice RVUs, including the impact of changes due to potentially misvalued codes.

• *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2014 impact on total allowed charges of the changes in the PE RVUs.

• *Column E (Combined Impact):* This column shows the estimated CY 2014 combined impact on total allowed charges of all the changes in the previous columns.

TABLE 71—CY 2014 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

Specialty	Allowed charges (mil)	Impact of work and MP RVU changes (percent)	Impact of PE RVU changes (percent)	Combined impact (percent)
(A)	(B)	(C)	(D)	(E)
TOTAL	$86,995	2	−2	0
01—ALLERGY/IMMUNOLOGY	213	1	−4	−3
02—ANESTHESIOLOGY	1,862	4	−1	3
03—CARDIAC SURGERY	355	3	−1	2
04—CARDIOLOGY	6,425	2	0	2
05—COLON AND RECTAL SURGERY	158	2	−2	0
06—CRITICAL CARE	273	3	−1	2
07—DERMATOLOGY	3,113	2	−4	−2
08—EMERGENCY MEDICINE	2,929	3	0	3
09—ENDOCRINOLOGY	447	2	−2	0
10—FAMILY PRACTICE	6,358	2	−1	1
11—GASTROENTEROLOGY	1,901	3	−2	1
12—GENERAL PRACTICE	528	2	−2	0
13—GENERAL SURGERY	2,236	3	−2	1
14—GERIATRICS	231	3	−1	2
15—HAND SURGERY	151	2	−2	0
16—HEMATOLOGY/ONCOLOGY	1,890	2	−3	−1
17—INFECTIOUS DISEASE	635	3	−1	2
18—INTERNAL MEDICINE	11,416	3	−2	1
19—INTERVENTIONAL PAIN MGMT	640	2	−3	−1
20—INTERVENTIONAL RADIOLOGY	219	2	−6	−4
21—MULTISPECIALTY CLINIC/OTHER PHY	79	2	−2	0
22—NEPHROLOGY	2,123	3	−2	1
23—NEUROLOGY	1,498	2	−4	−2
24—NEUROSURGERY	712	2	−1	1
25—NUCLEAR MEDICINE	51	2	−1	1
27—OBSTETRICS/GYNECOLOGY	688	2	−2	0
28—OPHTHALMOLOGY	5,592	2	−2	0
29—ORTHOPEDIC SURGERY	3,683	2	−2	0
30—OTOLARNGOLOGY	1,128	2	−4	−2
31—PATHOLOGY	1,134	3	−8	−5
32—PEDIATRICS	63	3	−3	0
33—PHYSICAL MEDICINE	999	3	−3	0
34—PLASTIC SURGERY	367	2	−2	0
35—PSYCHIATRY	1,165	3	−1	2
36—PULMONARY DISEASE	1,775	3	−2	1
37—RADIATION ONCOLOGY	1,783	1	−6	−5
38—RADIOLOGY	4,635	2	−3	−1
39—RHEUMATOLOGY	551	2	−5	−3
40—THORACIC SURGERY	332	3	−1	2
41—UROLOGY	1,858	2	−4	−2
42—VASCULAR SURGERY	925	2	−4	−2
43—AUDIOLOGIST	56	2	−1	1
44—CHIROPRACTOR	722	3	−1	2
45—CLINICAL PSYCHOLOGIST	579	4	−1	3
46—CLINICAL SOCIAL WORKER	408	4	−1	3
47—DIAGNOSTIC TESTING FACILITY	779	0	−7	−7
48—INDEPENDENT LABORATORY **	812	1	−27	−26
49—NURSE ANES/ANES ASST	1,055	4	0	4
50—NURSE PRACTITIONER	1,937	3	−2	1
51—OPTOMETRY	1,106	2	−2	0
52—ORAL/MAXILLOFACIAL SURGERY	44	2	−4	−2
53—PHYSICAL/OCCUPATIONAL THERAPY	2,797	2	−1	1
54—PHYSICIAN ASSISTANT	1,405	3	−2	1
55—PODIATRY	1,975	2	−2	0
56—PORTABLE X-RAY SUPPLIER	110	1	−2	−1

TABLE 71—CY 2014 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *—Continued

Specialty	Allowed charges (mil)	Impact of work and MP RVU changes (percent)	Impact of PE RVU changes (percent)	Combined impact (percent)
(A)	(B)	(C)	(D)	(E)
57—RADIATION THERAPY CENTERS	62	0	−13	−13
98—OTHER	25	3	−2	1

* Table 71 shows only the payment impact on PFS services. These impacts use a constant conversion factor and thus do not include the effects of the January 2014 conversion factor change required under current law.
** PFS Payments only, which account for ~17% of Independent Laboratory payments from Medicare.

Table 72 shows the estimated impact of selected policy proposals on total allowed charges, by specialty. The following is an explanation of the information represented in Table 72:

- *Column A (Specialty):* The Medicare specialty code as reflected in our physician/supplier enrollment files.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2012 utilization and CY 2013 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of 2012 Claims data, 90 Percent Equipment Utilization Assumption, Ultrasound Changes, and Other Minor Changes):* This column shows the estimated CY 2014 impact on total allowed charges of the changes in the RVUs due to the 90 percent equipment utilization assumption discussed in section II.A.2.f. of this proposed rule, ultrasound changes discussed in section II.A.5, the use of CY 2012 claims data to model payment rates, and all other proposals that result in minimal redistribution of payments under the PFS.
- *Column D (Impact of OPPS/ASC cap):* This column shows the estimated CY 2014 impact on total allowed charges of the changes in the RVUs resulting from our proposed policy discussed in section II.A.4. of this proposed rule.
- *Column E (Impact of MEI Revision):* This column shows the estimated CY 2014 combined impact on total allowed charges of the changes in the RVUs resulting from our proposed policy to adjust the RVUs to match the proposed revised MEI weights.
- *Column F (Cumulative Impact):* This column shows the estimated CY 2014 combined impact on total allowed charges of all the proposed changes in the previous columns.

TABLE 72—CY 2014 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY BY SELECTED PROPOSAL*

Specialty	Allowed charges (mil)	Impact of 2012 claims data, 90% utilization assumption, ultrasound changes, and other minor changes (percent)	Impact of OPD/ASC cap (percent)	Impact of MEI revision (percent)	Total (cumulative) impact (percent)
(A)	(B)	(C)	(D)	(E)	(F)
TOTAL	$86,995	0%	0%	0%	0%
01—ALLERGY/IMMUNOLOGY	213	−1	0	−2	−3
02—ANESTHESIOLOGY	1,862	0	0	3	3
03—CARDIAC SURGERY	355	0	0	2	2
04—CARDIOLOGY	6,425	2	0	0	2
05—COLON AND RECTAL SURGERY	158	0	0	0	0
06—CRITICAL CARE	273	0	0	2	2
07—DERMATOLOGY	3,113	0	0	−2	−2
08—EMERGENCY MEDICINE	2,929	0	0	3	3
09—ENDOCRINOLOGY	447	−1	1	0	0
10—FAMILY PRACTICE	6,358	0	1	0	1
11—GASTROENTEROLOGY	1,901	0	0	1	1
12—GENERAL PRACTICE	528	0	0	0	0
13—GENERAL SURGERY	2,236	0	0	1	1
14—GERIATRICS	231	0	1	1	2
15—HAND SURGERY	151	−1	1	0	0
16—HEMATOLOGY/ONCOLOGY	1,890	−1	1	−1	−1
17—INFECTIOUS DISEASE	635	0	0	2	2
18—INTERNAL MEDICINE	11,416	0	1	0	1
19—INTERVENTIONAL PAIN MGMT	640	−1	0	0	−1
20—INTERVENTIONAL RADIOLOGY	219	−1	−2	−1	−4
21—MULTISPECIALTY CLINIC/OTHER PHY	79	−1	0	1	0

TABLE 72—CY 2014 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY BY SELECTED PROPOSAL*—Continued

Specialty	Allowed charges (mil)	Impact of 2012 claims data, 90% utilization assumption, ultrasound changes, and other minor changes (percent)	Impact of OPD/ASC cap (percent)	Impact of MEI revision (percent)	Total (cumulative) impact (percent)
(A)	(B)	(C)	(D)	(E)	(F)
22—NEPHROLOGY	2,123	0	0	1	1
23—NEUROLOGY	1,498	0	−1	−1	−2
24—NEUROSURGERY	712	0	0	1	1
25—NUCLEAR MEDICINE	51	0	1	0	1
27—OBSTETRICS/GYNECOLOGY	688	0	0	0	0
28—OPHTHALMOLOGY	5,592	0	1	−1	0
29—ORTHOPEDIC SURGERY	3,683	−1	1	0	0
30—OTOLARNGOLOGY	1,128	−1	0	−1	−2
31—PATHOLOGY	1,134	1	−6	0	−5
32—PEDIATRICS	63	0	0	0	0
33—PHYSICAL MEDICINE	999	−1	1	0	0
34—PLASTIC SURGERY	367	0	1	−1	0
35—PSYCHIATRY	1,165	0	0	2	2
36—PULMONARY DISEASE	1,775	0	1	0	1
37—RADIATION ONCOLOGY	1,783	1	−4	−2	−5
38—RADIOLOGY	4,635	−1	0	0	−1
39—RHEUMATOLOGY	551	−3	1	−1	−3
40—THORACIC SURGERY	332	0	0	2	2
41—UROLOGY	1,858	−1	0	−1	−2
42—VASCULAR SURGERY	925	1	−3	0	−2
43—AUDIOLOGIST	56	0	1	0	1
44—CHIROPRACTOR	722	1	1	0	2
45—CLINICAL PSYCHOLOGIST	579	0	0	3	3
46—CLINICAL SOCIAL WORKER	408	0	0	3	3
47—DIAGNOSTIC TESTING FACILITY	779	−4	0	−3	−7
48—INDEPENDENT LABORATORY**	812	1	−25	−2	−26
49—NURSE ANES/ANES ASST	1,055	0	0	4	4
50—NURSE PRACTITIONER	1,937	0	1	0	1
51—OPTOMETRY	1,106	0	1	−1	0
52—ORAL/MAXILLOFACIAL SURGERY	44	0	−1	−1	−2
53—PHYSICAL/OCCUPATIONAL THERAPY	2,797	0	1	0	1
54—PHYSICIAN ASSISTANT	1,405	0	1	0	1
55—PODIATRY	1,975	−1	1	0	0
56—PORTABLE X-RAY SUPPLIER	110	1	1	−3	−1
57—RADIATION THERAPY CENTERS	62	0	−8	−5	−13
98—OTHER	25	0	1	0	1

*Table 72 shows only the payment impact on PFS services. These impacts use a constant conversion factor and thus do not include the effects of the January 2014 conversion factor change required under current law.

**PFS Payments only, which account for ~17% of Independent Laboratory payments.

2. CY 2014 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to two major factors. The first factor, as discussed in section II.A.4. of this proposed rule, is our proposal to cap the payments for certain nonfacility services at the facility rate plus the lower of the OPPS or ASC payment. The second factor, as discussed in section II.D., is our proposal to revise the Medicare Economic Index (MEI) and adjust the RVUs to match the new weights for work, PE, and MP.

In addition, a number of other changes contribute to the impacts shown in Table 71. These include a statutory change that requires us to use a 90 percent equipment utilization rate rather than the previously used 75 percent for expensive diagnostic imaging equipment as discussed in section II.A.2.f of this proposed rule, proposals to update direct practice expense inputs, as discussed in section II.A.5. of this proposed rule and proposals to adjust time for some services, as discussed in section II.B.3.c. of this proposed rule.

Table 72 shows the same information as provided in Table 71, but rather than isolating the policy impact on physician work, practice expense, and malpractice separately, Table 72 shows the impact of varied proposed policies on total RVUs.

b. Combined Impact

Column E of Table 71 and column F of Table 72 display the estimated CY 2014 combined impact on total allowed charges by specialty of all the proposed RVU changes. These impacts range from an increase of 3 percent for clinical social workers, clinical psychologists, nurse anesthetists, and emergency medicine, to a decrease of 26 percent for independent laboratories. Again, these impacts are estimated prior to the application of the negative CY 2014

conversion factor (CF) update applicable under the current statute.

Table 73 (Impact of Proposed Rule on CY 2014 Payment for Selected Procedures (Based on the March 2013 Preliminary Physician Update)) shows the estimated impact on total payments for selected high volume procedures of all of the changes discussed previously. We have included CY 2014 payment rates with and without the effect of the CY 2014 negative PFS CF update for comparison purposes. We selected these procedures from among the most commonly furnished by a broad spectrum of physician specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A of this proposed rule.

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TABLE 73: Impact of Proposed Rule on CY 2014 Payment for Selected Procedures (Based on the March 2013 Preliminary Physician Update)*

			Facility					Non-Facility				
CPT/ HCPCS [1]	MOD	Short Descriptor	CY 2013 [2]	CY 2014 [3] (pre update)	% Change (pre update)	CY 2014 [4] (post update)	% Change (post update)	CY 2013 [2]	CY 2014 [3] (pre update)	% Change (pre update)	CY 2014 [4] (post update)	% Change (post update)
11721		Debride nail 6 or more	$24.50	$25.32	3%	$19.04	-22%	$44.91	$45.29	1%	$34.06	-24%
17000		Destruct premalg lesion	$57.16	$57.42	0%	$43.18	-24%	$83.36	$81.67	-2%	$61.42	-26%
27130		Total hip arthroplasty	$1,454.48	$1,481.54	2%	$1,114.10	-23%	NA	NA	NA	NA	NA
27244		Treat thigh fracture	$1,242.18	$1,262.91	2%	$949.69	-24%	NA	NA	NA	NA	NA
27447		Total knee arthroplasty	$1,552.81	$1,582.11	2%	$1,189.73	-23%	NA	NA	NA	NA	NA
33533		Cabg arterial single	$1,906.31	$1,944.12	2%	$1,461.95	-23%	NA	NA	NA	NA	NA
35301		Rechanneling of artery	$1,096.22	$1,112.04	1%	$836.24	-24%	NA	NA	NA	NA	NA
43239		Upper gi endoscopy biopsy	$174.54	$177.26	2%	$133.29	-24%	$359.28	$347.74	-3%	$261.49	-27%
66821		After cataract laser surgery	$325.26	$323.84	0%	$243.52	-25%	$344.99	$342.39	-1%	$257.47	-25%
66984		Cataract surg w/iol 1 stage	$667.87	$673.00	1%	$506.09	-24%	NA	NA	NA	NA	NA
67210		Treatment of retinal lesion	$520.55	$523.21	1%	$393.45	-24%	$538.92	$540.69	0%	$406.59	-25%
71010		Chest x-ray 1 view frontal	NA	NA	NA	NA	NA	$23.82	$23.90	0%	$17.97	-25%
71010	26	Chest x-ray 1 view frontal	$8.85	$9.27	5%	$6.97	-21%	$8.85	$9.27	5%	$6.97	-21%
77056		Mammogram both breasts	NA	NA	NA	NA	NA	$114.66	$114.49	0%	$86.09	-25%
77056	26	Mammogram both breasts	$42.19	$43.87	4%	$32.99	-22%	$42.19	$43.87	4%	$32.99	-22%

			Facility					Non-Facility				
CPT/ HCPCS[1]	MOD	Short Descriptor	CY 2013[2]	CY 2014[3] (pre update)	% Change (pre update)	CY 2014[4] (post update)	% Change (post update)	CY 2013[2]	CY 2014[3] (pre update)	% Change (pre update)	CY 2014[4] (post update)	% Change (post update)
77057		Mammogram screening	NA	NA	NA	NA	NA	$81.66	$81.32	0%	$61.15	-25%
77057	26	Mammogram screening	$34.02	$35.31	4%	$26.55	-22%	$34.02	$35.31	4%	$26.55	-22%
77427		Radiation tx management x5	$178.28	$185.46	4%	$139.46	-22%	$178.28	$185.46	4%	$139.46	-22%
88305	26	Tissue exam by pathologist	$36.74	$38.16	4%	$28.70	-22%	$36.74	$38.16	4%	$28.70	-22%
90935		Hemodialysis one evaluation	$71.11	$73.47	3%	$55.25	-22%	NA	NA	NA	NA	NA
92012		Eye exam establish patient	$53.08	$54.92	3%	$41.30	-22%	$87.44	$86.67	-1%	$65.17	-25%
92014		Eye exam&tx estab pt 1/>vst	$80.29	$82.74	3%	$62.22	-23%	$126.23	$125.90	0%	$94.67	-25%
93000		Electrocardiogram complete	NA	NA	NA	NA	NA	$18.37	$18.19	-1%	$13.68	-26%
93010		Electrocardiogram report	$8.17	$8.56	5%	$6.44	-21%	$8.17	$8.56	5%	$6.44	-21%
93015		Cardiovascular stress test	NA	NA	NA	NA	NA	$79.61	$77.75	-2%	$58.47	-27%
93307	26	Tte w/o doppler complete	$44.23	$46.01	4%	$34.60	-22%	$44.23	$46.01	4%	$34.60	-22%
93458	26	L hrt artery/ventricle angio	$315.73	$324.55	3%	$244.06	-23%	$315.73	$324.55	3%	$244.06	-23%
98941		Chiropract manj 3-4 regions	$30.62	$31.39	2%	$23.60	-23%	$36.40	$37.45	3%	$28.16	-23%
99203		Office/outpatient visit new	$75.19	$77.75	3%	$58.47	-22%	$108.19	$108.42	0%	$81.53	-25%
99213		Office/outpatient visit est	$49.67	$51.71	4%	$38.89	-22%	$72.81	$72.76	0%	$54.71	-25%
99214		Office/outpatient visit	$76.55	$79.18	3%	$59.54	-22%	$106.83	$107.35	0%	$80.73	-24%

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CPT/ HCPCS [1]	MOD	Short Descriptor	Facility					Non-Facility				
			CY 2013[2]	CY 2014[3] (pre update)	% Change (pre update)	CY 2014[4] (post update)	% Change (post update)	CY 2013[2]	CY 2014[3] (pre update)	% Change (pre update)	CY 2014[4] (post update)	% Change (post update)
		est										
99222		Initial hospital care	$134.73	$138.38	3%	$104.06	-23%	NA	NA	NA	NA	NA
99223		Initial hospital care	$198.01	$203.65	3%	$153.14	-23%	NA	NA	NA	NA	NA
99231		Subsequent hospital care	$38.11	$39.23	3%	$29.50	-23%	NA	NA	NA	NA	NA
99232		Subsequent hospital care	$70.09	$72.40	3%	$54.44	-22%	NA	NA	NA	NA	NA
99233		Subsequent hospital care	$101.05	$104.14	3%	$78.31	-22%	NA	NA	NA	NA	NA
99236		Observ/hosp same date	$212.30	$218.63	3%	$164.41	-23%	NA	NA	NA	NA	NA
99239		Hospital discharge day	$104.79	$107.35	2%	$80.73	-23%	NA	NA	NA	NA	NA
99283		Emergency dept visit	$59.88	$61.70	3%	$46.40	-23%	NA	NA	NA	NA	NA
99284		Emergency dept visit	$114.66	$118.05	3%	$88.77	-23%	NA	NA	NA	NA	NA
99291		Critical care first hour	$217.75	$223.26	3%	$167.89	-23%	$272.18	$273.91	1%	$205.98	-24%
99292		Critical care addl 30 min	$109.55	$112.70	3%	$84.75	-23%	$120.78	$123.05	2%	$92.53	-23%
99348		Home visit est patient	NA	NA	NA	NA	NA	$82.34	$84.53	3%	$63.56	-23%
99350		Home visit est patient	NA	NA	NA	NA	NA	$173.52	$177.61	2%	$133.56	-23%
G0008		Immunization admin	NA	NA	NA	NA	NA	$25.86	$24.97	-3%	$18.77	-27%

[1] CPT codes and descriptions are copyright 2012 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

[2] Payments based on the 2013 conversion factor of 34.0230.

[3] Payments based on the 2013 conversion factor of 34.0230, adjusted to 35.6653 to include the budget neutrality adjustment.

[4] Payments based on the estimated 2014 conversion factor of 25.7109 adjusted to 26.8199 to include a budget neutrality adjustment.

D. Effect of Proposed Changes to Medicare Telehealth Services Under the PFS

As discussed in section II.E.3 of this proposed rule, we are proposing to refine our definition of rural as it applies to HPSAs eligible for telehealth services as well as add transitional care management services to the list of Medicare telehealth services. While we expect these changes to increase access to care in rural areas, based on recent utilization of current Medicare telehealth services, including services similar to transitional care management, we estimate no significant impact on PFS expenditures from the proposed additions.

E. Geographic Practice Cost Indices (GPCIs)

Based upon statutory requirements we are proposing to update the GPCIs for each Medicare payment locality. The proposed GPCIs incorporate the use of updated data and cost share weights as discussed in II.E. The Act requires that updated GPCIs be phased in over two years. Addendum D shows the estimated effects of the revised GPCIs on area GAFs for the transition year (CY 2014) and the fully implemented year (CY 2015). The GAFs reflect the use of the updated underlying GPCI data, and the proposed revised cost share weights. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use the GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual geographic adjustment to payment for any actual service will be different from the GAF to the extent that the proportions of work, PE and malpractice expense RVUs for the service differ from those of the GAF.

The most significant changes occur in 22 payment localities where the fully implemented (CY 2015) GAF moves up by more than 1 percent (11 payment localities) or down by more than 2 percent (11 payment localities). The impacts on the proposed GPCIs are primarily attributed to the expiration of the 1.000 work GPCI floor. The use of updated underlying GPCI data and cost share weights has a minimal impact on locality GAFs. The total impact of the GPCI revisions is shown in the 2015 GPCI values of Addendum E.

We note that the proposed CY 2014 physician work GPCIs and summarized geographic adjustment factors (GAFs) published in Addenda D and E reflect the elimination of the 1.0 work GPCI floor provided in section 1848 (e)(1)(E) of the Act, which is set to expire prior to the implementation of the CY 2014 PFS.

F. Other Provisions of the Proposed Regulation

1. Rebasing and Revising Medicare Economic Index

The preliminary estimate of the proposed changes to the MEI for CY 2014 is a 0.1 percent decrease. This is based on an estimated 0.8 percent increase for CY 2014 under the current MEI compared to a 0.7 percent increase for CY 2014 under the proposed revised MEI.''

2. Coverage of Items and Services Furnished in FDA-Approved Investigational Device Exemption (IDE) Clinical Trials

We are proposing a transparent centralized review process that would be more efficient by reducing the burden for stakeholders. Once the IDE coverage process is centralized, there will be a single entity making the IDE coverage decision. This also eliminates duplicative reviews by Medicare local contractors and the numerous applications sent to contractors by stakeholders requesting IDE coverage. We believe that a centralized review process will not significantly reduce the number of IDE devices currently covered. Therefore, this rule will not result in an extra burden to the public.

3. Ultrasound Screening for Abdominal Aortic Aneurysms

As discussed in section III.B. of this proposed rule, section 1861(s)(2)(AA) of the Act, with implementing regulations at § 410.19, authorizes Medicare coverage of ultrasound screening for abdominal aortic aneurysms (''AAA screening''). We are proposing to modify § 410.19 to allow coverage of one-time AAA screening without receiving a referral as part of the IPPE, for beneficiaries that meet certain other eligibility criteria (a family history of AAA or, for men aged 65–75, a history of smoking). Approximately 45 percent of men aged 65–75 have a history of smoking. It is unknown how many individuals have a family history of AAA or how many beneficiaries will avail themselves of this benefit. Therefore, the impact of this change is unknown for CY 2014.

4. Modification to Medicare Coverage of Colorectal Cancer Screening

As discussed in section III.C. of this proposed rule, sections 1861(s)(2)(R) and 1861(pp)(1) of the Act, and implementing regulations at 42 CFR 410.37 authorize Medicare coverage of screening FOBT. We are proposing to modify § 410.37(b) to allow attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists to furnish orders for screening FOBTs. While there may be an increase in utilization, particularly in rural areas, it is unknown how many individuals will avail themselves of this benefit. Therefore, the impact of this change is unknown for CY 2014.

5. Ambulance Fee Schedule

As discussed in section III.D. of this proposed rule, section 604(a) through (c) of the ATRA require the extension of certain add-on payments for ground ambulance services and the extension of certain rural area designations for purposes of air ambulance payment. In addition, as discussed in section III.D. of this proposed rule, section 637 of the ATRA (which added section 1834(l)(15) of the Act) specifies that the fee schedule amount otherwise applicable under the preceding provisions of section 1834(l) of the Act shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility. The ambulance extender provisions and the mandated 10 percent rate decrease discussed above are enacted through legislation that is self-implementing. We are proposing to amend the regulation text at § 414.610 only to conform the regulations to these self-implementing statutory requirements. As a result, we are not making any policy proposals associated with these legislative provisions and there is no associated regulatory impact.

6. Clinical Laboratory Fee Schedule

We are proposing to add language to the Code of Federal Regulations to codify authority provided by statute and to establish a process under which we will systematically reexamine the payment amounts established under the CLFS to determine if changes in technology for the delivery of that service warrant an adjustment to the payment amount. We are also proposing a definition for the term technological changes. Adjustments made under the new process could both increase fee schedule amounts and provide for reductions in existing amounts. We cannot estimate a net impact at this time.

7. Liability for Overpayments to or on Behalf of Individuals Including Payments to Providers or Other Persons

As discussed in section III.M. of this proposed rule, we are proposing to change the timing of the triggering event for the ''without fault'' and ''against equity and good conscience'' presumptions. As a result, there would be an estimated savings of $0.5 billion over 10 years.

8. Physician Compare Web Site

There will be no impact for the Physician Compare Web site because we are not collecting any information for the Physician Compare Web site.

9. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System (PQRS)

In the CY 2013 PFS final rule with comment period, we provided estimates related to the impact of the requirements we finalized for the PQRS for 2014. Since we are making additional proposals for 2014, this section modifies the impact statement provided for 2014 in the CY 2013 PFS final rule with comment period. Please note that we will base our estimates on information found in the 2011 Physician Quality Reporting System and eRx Reporting Experience and Trends (hereinafter ''the PQRS Reporting Experience''). This report contains the latest data we have gathered on PQRS participation. The PQRS Reporting Experience is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/*. According to the 2011 Reporting Experience Report, over 1 million professionals were eligible to participate in the PQRS. A total of $261,733,236 in PQRS incentives was paid by CMS for the 2011 program year, which encompassed 26,515 practices that included 266,521 eligible professionals (or approximately 27 percent of the professionals eligible to participate). The average incentive earned for PQRS in 2011 per each individually-participating eligible professional was $1,059.

As we noted in our impact statement last year, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the PQRS would rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively. We believe our estimate of 400,000 eligible professionals participating in PQRS in 2014 is accurate.

With respect to the estimate amount of incentives earned, for 2014, eligible professionals can earn a 0.5 percent incentive (that is, a bonus payment equal to 0.5 percent of the total allowed Part B charges for covered professional services under the PFS furnished by the eligible professional during the reporting period) for satisfactory reporting, a reduction of 1.0 percent from 2011. Based on information drawn from the 2011 Reporting Experience and our participation estimate, we believe that, out of the 400,000 eligible professionals we expect to participate in the PQRS in 2014, the PQRS will distribute 2014 incentives to approximately (27 percent of 1 million eligible professionals) 270,000 eligible professionals. At $1,059 per eligible professional, the PQRS would distribute approximately $286 million in incentive payments in 2014. We believe these incentive payments will help offset the cost eligible professionals may undertake for participating in the PQRS for the applicable year.

We note that the total burden associated with participating in the PQRS is the time and effort associated with indicating intent to participate in the PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assume the following:

- The proposals for reporting for the PQRS for the 2014 incentive and 2016 payment adjustment would be established as proposed in this CY 2014 Medicare PFS proposed rule.
- For an eligible professional or group practice using the claims, registry, or EHR-based reporting mechanisms, we assume that the eligible professional or group practice would attempt to report PQRS quality measures data with the intention of earning the 2014 PQRS incentive. Therefore, an eligible professionals or group practice would report on 9 measures.
- With respect to labor costs, we believe that a billing clerk will handle the administrative duties associated with participating, while a computer analyst will handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately $16/hour whereas the mean hourly wage for a computer analyst is approximately $40/hour.

For an eligible professional who wishes to participate in the PQRS as an individual, the eligible professional need not indicate his/her intent to participate. The eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in the PQRS are based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice would spend 5 hours—which includes 2 hours to review the PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in the PQRS would be approximately $80 ($16/hour × 5 hours).

With respect to an eligible professional who participates in the PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The PQRS collects QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN: 0938–0999). Based on our experience with Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims will range from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 9 measures would range from 2.25 minutes to 108 minutes. Using an average labor cost of $40/hour, we estimate that time cost of reporting for an eligible professional via claims would range from $1.50 (2.25 minutes or 0.0375 hours × $40/hour) to $72.00 (108 minutes or 1.8 hours × $40/hour) per reported case. With respect to how many cases an eligible professional would report when using the claims-based reporting mechanism, we proposed that an eligible professional would need to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which an eligible professional would report would vary depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent, we found that the median number of reporting cases for each measure was 9. Since we are proposing to reduce the reporting threshold to 50 percent, we estimate that the average number of reporting cases for each measure would be reduced to 6. Based on these estimates, we estimate that the

total cost of reporting for an eligible professional choosing the claims-based reporting mechanism would range from ($1.50/per reported case × 6 reported cases) $9.00 to ($72.00/reported case × 6 reported cases) $432.

With respect to an eligible professional or group practice who participates in the PQRS via a qualified registry, direct EHR product, EHR data submission vendor product, or qualified clinical data registry, we believe there would be little to no burden associated for an eligible professional or group practice to report PQRS quality measures data to CMS, because the selected reporting mechanism submits the quality measures data for the eligible professional. While we note that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, EHR data submission vendor, or qualified clinical data registry, we believe that an eligible professional or group practice would not purchase a qualified registry, direct EHR product, EHR data submission vendor product, or qualified clinical data registry solely for the purpose of reporting PQRS quality measures. Therefore, we have not included the cost of purchasing a qualified registry, direct EHR, EHR data submission vendor product, or qualified clinical data registry in our burden estimates.

Unlike eligible professionals who choose to report individually, we note that eligible professionals choosing to participate as part of a group practice under the GPRO must indicate their intent to participate in the PQRS as a group practice. The total burden for group practices who submit PQRS quality measures data via the proposed GPRO web-interface would be the time and effort associated with submitting this data. To submit quality measures data for the PQRS, a group practice would need to (1) be selected to participate in the PQRS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in the PQRS as a GPRO, we believe it would take approximately 6 hours—including 2 hours to decide to participate in the PQRS as a GPRO, 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials—for a group practice to be selected to participate in the PQRS GPRO for the applicable year. Therefore, we estimate that the cost of undergoing the GPRO selection process would be ($16/hour × 6 hours) $96. With respect to reporting, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimate the burden associated with a group practice completing the data collection interface would be approximately 79 hours. Therefore, we estimate that the report cost for a group practice to submit PQRS quality measures data for the proposed reporting options in an applicable year would be ($40/hour × 79 hours) $3,160.

Aside from the burden of eligible professionals and group practices participating in the PQRS, we believe that vendors of registries, qualified clinical data registries, direct EHR products, and EHR data submission vendor products incur costs associated with participating in the PQRS. Please note that we have proposed requirements for a new reporting mechanism in this CY 2014 PFS proposed rule—the qualified clinical data registry. For purpose of these burden estimates, we believe that, at least in its initial stage, vendors of a qualified clinical data registry would have burden estimates similar to traditional registries, as we believe many of the vendors seeking to become qualified as a clinical data registry in the PQRS will be existing qualified registries.

With respect to qualified registries and qualified clinical data registries, the total burden for qualified registries who submit PQRS Quality Measures Data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed program years for PQRS, a registry would need to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process for both traditional registries and clinical data registries, we estimate that it will take a total of 10 hours—including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wishes to report using a CMS-provided measure flow, and 5 hours to complete an XML submission—to become qualified to report PQRS quality measures data. Therefore, we estimate that it would cost a traditional registry and clinical data registry ($16.00/hour × 10 hours) $160 to become qualified to submit PQRS quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, we believe the burden associated with reporting is the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. We believe, however, that registries already perform these functions for its eligible professionals irrespective of participating in the PQRS. Therefore, we believe there would be little to no additional burden associated with reporting PQRS quality measures data. Whether there is any additional reporting burden will vary with each registry, depending on the registry's level of savvy with submitting quality measures data for the PQRS.

With respect to EHR products, the total burden for direct EHR products and EHR data submission vendors who submit PQRS Quality Measures Data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed program years under the PQRS, a direct EHR product or EHR data submission vendor would need to report quality measures data on behalf of its eligible professionals. Please note that we are not proposing to continue to require direct EHR products and EHR data submission vendors to become qualified to submit PQRS quality measures data.

In addition to the GPRO web interface, please note that we have proposed a new reporting mechanism that would be available to group practices comprised of 25+ eligible professionals: the certified survey vendor. With respect to using a certified survey vendor, we believe there would be little to no burden associated for a group practice to report the CG CAHPS survey data to CMS, because the selected reporting mechanism submitted the quality measures data for the group practice. While there may be start-up costs associated with purchasing a certified survey vendor, we believe that a group practice would not purchase a certified survey vendor solely for the purpose of reporting the CG CAHPS survey for the PQRS. Therefore, we have not included the cost of purchasing a certified survey vendor in our burden estimates.

TABLE 74—ESTIMATED COSTS FOR REPORTING PQRS QUALITY MEASURES DATA PER ELIGIBLE PROFESSIONAL

	Estimated hours	Estimated cases	Number of measures	Hourly rate	Total cost
Individual Eligible Professional (EP): Preparation	5.0	1	N/A	$16	$80
Individual EP: Claims	1.8	6	9	40	3,888
Individual EP: Registry	N/A	1	N/A	N/A	Minimal
Individual EP: EHR	N/A	1	N/A	N/A	Minimal
Group Practice: Self-Nomination	6.0	1	N/A	16	96
Group Practice: Reporting	79	1	N/A	40	3,160

TABLE 75—ESTIMATED COSTS PER VENDOR TO PARTICIPATE IN THE PQRS

	Estimated hours	Hourly rate	Total cost
Registry: Self-Nomination	10	$16	$160

10. Medicare EHR Incentive Program

Please note that the requirements for meeting the clinical quality measures (CQM) component of achieving meaningful use for the EHR Incentive Program in 2014 were established in a standalone final rule published on September 4, 2012 (77 FR 53968). The proposals contained in this CY 2014 PFS proposed rule merely propose alternative methods to report CQMs to meet the CQM component of achieving meaningful use for the EHR Incentive Program in 2014. We believe any impacts these proposals would have are absorbed in the impacts discussion published in the EHR Incentive Program final rule published on September 4, 2012.

11. Medicare Shared Savings Program

Please note that the requirements for participating in the Medicare Shared Saving Program and the impacts of these requirements were established in the final rule for the Medicare Shared Savings Program that appeared in the **Federal Register** on November 2, 2011 (76 FR 67962). The proposals for the Medicare Shared Savings Program set forth in the CY 2014 MPFS proposed rule expand the incorporation of reporting requirements and incentive payments related to PQRS under section 1848 to include reporting requirements related to the payment adjustment. Since ACO participants and ACO provider/suppliers will not have to report PQRS separately to avoid the payment adjustment, this reduces the quality reporting burden for ACO participants participating in the Shared Savings Program. There is no impact for the additional proposals related to requirements for setting benchmarks or for scoring the CAHPS measure modules.

12. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

The changes to the Physician Feedback Program in section III.K. of this proposed rule would not impact CY 2014 physician payments under the Physician Fee Schedule. We anticipate that as we approach implementation of the value modifier, physicians will increasingly participate in the Physician Quality Reporting System to determine and understand how the value modifier could affect their payments.

13. Existing Standards for E-Prescribing Under Medicare Part D and Identification

This section of the proposed rule imposes no new requirements because use of the official Part D e-prescreening standards; NCPDP SCRIPT 10.6, Formulary and Benefit 3.0 are voluntary, and as such, it will not have a significant economic impact on a substantial number of small entities, small rural hospitals or state, local, or tribal governments or on the private sector.

14. Chiropractic Services Demonstration

As discussed in section III.M. of this proposed rule, we are continuing the recoupment of the $50 million in expenditures from this demonstration in order to satisfy the BN requirement in section 651(f)(1)(B) of the MMA. We initiated this recoupment in CY 2010 and this will be the fifth and final year. As discussed in the CY 2010 PFS final rule with comment period, we finalized a policy to recoup $10 million each year through adjustments to payments under the PFS for chiropractic CPT codes in CYs 2010 through 2014. For each year of this recoupment, we have provided OACT's projected chiropractic expenditures based on previous year's data. While OACT's projections have included the statutory reductions to physician payments, the statute was amended in each year to avoid these reductions. As a result, Medicare expenditures for chiropractic services during the recoupment were higher than the OACT projections. Chiropractic services expenditures during the recoupment period have been as follows: $540 million in 2010; $520 million in 2011; and $580 million in 2012. In total, CMS recouped $32.8 million over the years of 2010, 2011 and 2012. OACT now projects chiropractic expenditures to be approximately $580 million in 2013. A 2 percent recoupment percentage for chiropractic services would result in approximately $11.6 million in 2013. For the years 2010 through 2013, CMS would have recouped approximately $44.4 million of the $50 million required for budget neutrality.

CMS plans to recoup the remaining funds, approximately $5.6 million, and will reduce chiropractic CPT codes (CPT codes 98940, 98941, and 98942) by the appropriate percentage, which by our preliminary estimates is one percent if the approximately 25 percent reduction in physician payments takes effect in 2014. If the statute is amended to avoid the physician payment reduction, we will reduce the recoupment percentage as appropriate to ensure the recoupment does not exceed $50 million. For instance, if the statute is amended to provide for a zero percent PFS update, we would reduce the recoupment percentage to approximately 0.7 percent.

G. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those

policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

H. Impact on Beneficiaries

There are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, we believe that many of the proposed changes, including the refinements of the PQRS with its focus on measuring, submitting, and analyzing quality data; establishing the basis for the value-based payment modifier to adjust physician payment beginning in CY 2015; improved accuracy in payment through revisions to the inputs used to calculate payments under the PFS and the capping certain nonfacility services at the facility rate plus the lower of the OPPS or ASC rate; and revisions to payment for Part B drugs will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

Most of the aforementioned proposed policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 73, the CY 2013 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $108.05, which means that in CY 2013 a beneficiary would be responsible for 20 percent of this amount, or $21.61. Based on this proposed rule, using the current (CY 2013) CF of 34.0376, adjusted to 35.6652 to include budget neutrality, the CY 2014 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 73, is $113.15, which means that, in CY 2014, the proposed beneficiary coinsurance for this service would be $22.63.

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 76 (Accounting Statement), we have prepared an accounting statement showing the estimated expenditures associated with this proposed rule. This estimate includes the CY 2014 incurred benefit impact associated with the estimated CY 2014 PFS conversion factor update based on the FY 2014 President's Budget baseline.

TABLE 76—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2014 Annualized Monetized Transfers	Estimated decrease in expenditures of $19.6 billion for PFS conversion factor update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 2014 Annualized Monetized Transfers	Estimated increase in payment of $286 million.
From Whom To Whom?	Federal Government to eligible professionals who satisfactorily participate in the Physician Quality Reporting System (PQRS).
CY 2014 Annualized Monetized Transfers	Estimated decrease in expenditures of $50 million for liability for overpayments to or on behalf of individuals including payments to providers or other persons.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 77—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2014 Annualized Monetized Transfers of beneficiary cost coinsurance.	$29 million.
From Whom to Whom?	Beneficiaries to Federal Government.
Category	**Cost**
CY 2014 Annualized Monetized Cost to eligible professionals of Participating in the PQRS Program.	$66.6 million.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial ''Regulatory Flexibility Analysis.'' The previous analysis, together with the preceding portion of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services propose to amend 42 CFR chapters IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1862(m), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395y(m), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.201 is amended by adding paragraph (a)(3) and revising paragraph (b) to read as follows:

§ 405.201 Scope of subpart and definitions.

(a) * * *

(3) CMS identifies criteria for coverage of items and services furnished in IDE studies.

(b) *Definitions.* As used in this subpart—

Category A (Experimental) device refers to a device for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B (Nonexperimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

ClinicalTrials.gov refers to the National Institutes of Health's National Library of Medicine's online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Contractors refers to Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare items and services.

IDE stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

Pivotal studies or trials refer to clinical investigations designed to collect definitive evidence of the safety and effectiveness of a device for a specified intended use, typically in a statistically justified number of subjects. It may or may not be preceded by an early and/or a traditional feasibility study.

Routine care items and services refer to items and services that are otherwise generally available to Medicare beneficiaries (that is, there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are furnished in either the experimental or the control arms of a clinical trial and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical trial.

Superiority studies or trials refers to studies or trials that are intended to demonstrate at some prespecified level of confidence that the effect of an investigational treatment is superior to that of an active control by more than a prespecified margin.

■ 3. Section 405.207 is amended by revising paragraph (b)(2) to read as follows:

§ 405.207 Services related to a non-covered device.

* * * * *

(b) * * *

(2) Routine care items and services related to experimental/investigational (Category A) devices as defined in § 405.201(b); and furnished in conjunction with an FDA-approved clinical trial that meet the IDE study standards in § 405.212.

* * * * *

■ 4. Section 405.211 is revised to read as follows:

§ 405.211 Coverage of items and services in FDA approved IDE studies.

(a) *Requirements.* CMS review includes the following items and supporting materials as needed:

(1) The FDA approval letter.

(2) IDE study protocol.

(3) IRB approval letter.

(4) ClinicalTrial.gov identifier.

(b) *Coverage of routine care items and services for Category A devices.* Medicare may cover routine care items and services furnished in any FDA-approved Category A IDE study if the criteria in § 405.212(a)(1) through (13) are met. Medicare covers routine care items and services furnished in any FDA-approved Category A IDE study if the criteria in § 405.212(a) and (b) are met.

(c) *Coverage of Category B IDE devices and routine care.* Medicare may cover a Category B IDE device and routine care items and services furnished in any FDA-approved Category B IDE study if the criteria in § 405.212(a)(1) through (13) are met. Medicare covers a Category B IDE device and routine care items and services furnished in any FDA-approved Category B IDE study if the criteria in § 405.212(a) and (c) are met.

(d) *Coverage of Category A routine services and Category B IDE devices and routine care that do not wholly fall under § 405.212 (b) or (c).* If an IDE device is furnished in an FDA-approved IDE study that does not wholly fall under § 405.212(b) or (c), CMS considers whether the study's attainment of the criteria in § 405.212 (a) are sufficient to mitigate the failure to meet § 405.212(b) or (c).

(e) *Notification.* All CMS-approved IDE studies will be posted on the CMS coverage Web site and published in the **Federal Register**.

■ 5. Section 405.212 is added to read as follows:

§ 405.212 IDE study criteria.

(a) All category A and B IDE studies must conform to the following criteria for Medicare coverage under § 405.211:

(1) The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of patients who are represented by the Medicare-enrolled subjects.

(2) The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

(3) The study results are not anticipated to unjustifiably duplicate existing knowledge.

(4) The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to answer the research question(s) being asked in the study.

(5) The study is sponsored by an organization or individual capable of completing it successfully.

(6) The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR part 46.

(7) All aspects of the study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors.

(8) The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.

(9) Where appropriate, the clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this standard only if the disease or condition being studied is life threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options.

(10) The study is registered on the ClinicalTrials.gov Web site and/or the Registry of Patient Registries (RoPR) by the principal sponsor/investigator prior to the enrollment of the first study subject.

(11) The study protocol specifies the method and timing of public release of results on all pre-specified outcomes, including release of negative outcomes. The release should be hastened if the study is terminated early. The results must be made public within 24 months

of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

(12) The study protocol explicitly discusses subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the study. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

(13) The study protocol explicitly discusses how the results are or are not expected to be generalizable to subsections of the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

(b) Medicare covers routine care items and services in an FDA-approved Category A IDE study that meets the requirements in paragraph (a) of this section and the study is the following:

(1) A pivotal study.

(2) A superiority study design.

(c) Medicare covers the IDE device and routine care items and services in an FDA-approved Category B IDE study that meets the requirements in paragraph (a) of this section and the study is the following:

(1) A pivotal study.

(2) A superiority study design.

■ 6. Section 405.350 is amended by revising paragraph (c) to read as follows:

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

* * * * *

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the fifth year following the year in which notice was sent to such individual that such amount had been paid.

■ 7. Section 405.355 is amended by revising paragraph (b) to read as follows:

§ 405.355 Waiver of adjustment or recovery.

* * * * *

(b) Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault shall be deemed to be against equity and good conscience if the incorrect payment was made for items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act and if the determination that such payment was incorrect was made subsequent to the fifth year following the year in which notice of such payment was sent to such individual.

■ 8. Section 405.2413 is amended by—

■ A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.

■ B. Adding new paragraph (a)(4).

■ C. Revising newly redesignated paragraph (a)(5).

The revision and addition reads as follows:

§ 405.2413 Services and supplies incident to a physician's services.

(a) * * *

(4) Services and supplies must be furnished in accordance with applicable State law;

(5) Furnished under the direct supervision of a physician; and

* * * * *

■ 9. Section 405.2415 is amended by—

■ A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.

■ B. Adding new paragraph (a)(4).

■ C. Revising newly redesignated paragraph (a)(5).

■ D. Revising paragraph (b).

The revision and addition reads as follows:

§ 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.

(a) * * *

(4) Services and supplies must be furnished in accordance with applicable State law;

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner or a physician; and

* * * * *

(b) The direct supervision requirement is met in the case of a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to supervise such services under the written policies governing the rural health clinic.

* * * * *

■ 10. Section 405.2452 is amended by—

■ A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.

■ B. Adding new paragraph (a)(4).

■ C. Revising newly redesignated paragraph (a)(5).

■ D. Revising paragraph (b).

The revision and addition reads as follows:

§ 405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

(a) * * *

(4) Services and supplies must be furnished in accordance with applicable State law;

(5) Furnished under the direct supervision of a clinical psychologist, clinical social worker or physician; and

* * * * *

(b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist or clinical social worker is permitted to supervise such services under the written policies governing the Federally qualified health center.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 11. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd).

§ 410.19 [Amended]

■ 12. In § 410.19(a) amend the definition of ''eligible beneficiary'' by removing paragraph (1) and redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively.

■ 13. Section 410.26 is amended by—

■ A. Revising paragraph (a)(1).

■ B. Redesignating paragraph (b)(7) and (8) as paragraph (b)(8) and (9), respectively.

■ C. Adding new paragraph (b)(7).

The revision and addition reads as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(1)*Auxiliary personnel* means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the

individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner) and meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.

* * * * *

(b) * * *

(7) Services and supplies must be furnished in accordance with applicable State law.

* * * * *

■ 14. Section 410.37 is amended by revising paragraph (b) to read as follows:

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

* * * * *

(b) *Condition for coverage of screening fecal-occult blood tests.* Medicare Part B pays for a screening fecal-occult blood test if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist.

* * * * *

■ 15. Section 410.59 is amended by—

■ A. Adding paragraph (e)(1)(iv).

■ B. Revising paragraph (e)(2)(iv).

■ C. Adding paragraph (e)(2)(v).

The revision and additions reads as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

* * * * *

(e) * * *

(1) * * *

(iv) Outpatient occupational therapy services furnished by a CAH directly or under arrangements shall be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.

(2)* * *

(iv) Outpatient occupational therapy services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and

(v) Outpatient occupational therapy services furnished by a CAH directly or under arrangements.

* * * * *

■ 16. Section 410.60 is amended by—

■ A. Adding paragraph (e)(1)(iv).

■ B. Revising paragraph (e)(2)(v).

■ C. Adding paragraph (e)(2)(vi).

■ D. In paragraph (e)(3), removing the phrase ''or CAH'' .

The additions and revision read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

* * * * *

(e) * * *

(1) * * *

(iv) Outpatient physical therapy services furnished by a CAH directly or under arrangements shall be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.

(2) * * *

(v) Outpatient physical therapy and speech-language pathology services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and

(vi) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements.

* * * * *

■ 17. Section 410.71 is amended by revising paragraph (a)(2) to read as follows:

§ 410.71 Clinical psychologist services and services and supplies incident to clinical psychologist services.

(a) * * *

(2) Medicare Part B covers services and supplies incident to the services of a clinical psychologist if the requirements of § 410.26 are met.

* * * * *

■ 18. Section 410.74 is amended by revising paragraph (b) to read as follows:

§ 410.74 Physician assistants' services.

* * * * *

(b) *Services and supplies furnished incident to a physician assistant's services.* Medicare Part B covers services and supplies incident to the services of a physician assistant if the requirements of § 410.26 are met.

* * * * *

■ 19. Section 410.75 is amended by revising paragraph (d) to read as follows:

§ 410.75 Nurse practitioners' services.

* * * * *

(d) *Services and supplies incident to a nurse practitioners' services.* Medicare Part B covers services and supplies incident to the services of a nurse practitioner if the requirements of § 410.26 are met.

* * * * *

■ 20. Section 410.76 is amended by revising paragraph (d) to read as follows:

§ 410.76 Clinical nurse specialists' services.

* * * * *

(d) *Services and supplies furnished incident to clinical nurse specialists' services.* Medicare Part B covers services and supplies incident to the services of a clinical nurse specialist if the requirements of § 410.26 are met.

* * * * *

■ 21. Section 410.77 is amended by revising paragraph (c) to read as follows:

§ 410.77 Certified nurse-midwives' services: Qualifications and conditions.

* * * * *

(c) *Incident to services: Basic rule.* Medicare Part B covers services and supplies incident to the services of a certified nurse-midwife if the requirements of § 410.26 are met.

* * * * *

■ 22. Section 410.78 is amending by revising paragraph (b) introductory text and paragraph (b)(4) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) *General rule.* Medicare Part B pays for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every three days by the patient's admitting physician or practitioner), subsequent nursing facility care services (not including the Federally-mandated periodic visits under § 483.40(c) of this chapter and with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of ''hands on'' services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention services, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, behavioral counseling for obesity, and transitional care management services

furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

(4) Originating sites must be:

(i) Located in a health professional shortage area (as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) that is either outside of a Metropolitan Statistical Area (MSA) as of December 31st of the preceding calendar year or within a rural census tract of an MSA as determined by the Office of Rural Health Policy of the Health Resources and Services Administration as of December 31st of the preceding calendar year, or

(ii) Located in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act as of December 31st of the preceding year, or

(iii) An entity participating in a Federal telemedicine demonstration project that has been approved by, or receive funding from, the Secretary as of December 31, 2000 regardless of its geographic location.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 23. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 24. Section 411.15 is amended by revising paragraph (o)(2) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(o) * * *

(2) Furnished in accordance with the CMS criteria established in § 405.211(b).

* * * * *

PART 414–PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 25. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 26. Section 414.65 is amended by revising paragraph (a)(1) to read as follows:

§ 414.65 Payment for telehealth services.

(a) * * *

(1) The Medicare payment amount for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every 3 days by the patient's admitting physician or practitioner), subsequent nursing facility care services (with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of ''hands on'' services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, behavioral counseling for obesity, and transitional care management services furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

(i) *Emergency department or initial inpatient telehealth consultations.* The Medicare payment amount for emergency department or initial inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to initial hospital care provided by a physician or practitioner.

(ii) *Follow-up inpatient telehealth consultations.* The Medicare payment amount for follow-up inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to subsequent hospital care provided by a physician or practitioner.

* * * * *

■ 27. Section 414.90 is amended by—

■ A. Amending paragraph (b) to—

■ 1. Revise the definition of ''Administrative claims''.

■ 2. Add the definition of ''Certified survey vendor''.

■ 3. Revise the definition of ''Measures group''.

■ 4. Add the definition of ''Qualified clinical data registry''.

■ B. Adding paragraphs (c)(5), (e)(2), and (f)(4).

■ C. Revising the paragraph headings to paragraphs (f) introductory text, (g) introductory text, and (h) introductory text.

■ D. Revising paragraphs (g)(3) introductory text.

■ E. Redesignating paragraph (g)(3)(v) as (g)(3)(vi).

■ F. Adding new paragraph (g)(3)(v).

■ G. Revising paragraph (h)(3) introductory text.

■ H. Adding paragraph (h)(3)(vi).

■ I. Revising paragraph (j).

The revisions and additions read as follows:

§ 414.90 Physician Quality Reporting System.

* * * * *

(b) * * *

Administrative claims means a reporting mechanism under which an eligible professional or group practice uses claims to report data on PQRS quality measures. Under this reporting mechanism, CMS analyzes claims data to determine which measures an eligible professional or group practice reports.

Certified survey vendor means a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS.

* * * * *

Measures group means a subset of six or more Physician Quality Reporting System measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.

* * * * *

Qualified clinical data registry means a CMS-approved entity that has self-nominated and successfully completed a qualification process that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A qualified clinical data registry must do the following functions:

(i) Submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible professionals have satisfactorily participated in PQRS. A qualified clinical data registry must have in place mechanisms for the transparency of data elements and

specifications, risk models, and measures.

(ii) Provide timely feedback, at least quarterly on the measures at the individual participant level for which the qualified clinical data registry reports on the eligible professional's behalf for purposes of the individual eligible professional's satisfactory participation in the clinical quality data registry.

(iii) Possess benchmarking capacity that measures the quality of care an eligible professional provides with other eligible professionals performing the same or similar functions.

* * * * *

(c) * * *

(5) The Secretary shall treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (g) of this section), if the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry (as defined in paragraph (b) of this section).

(i) For purposes of this paragraph, the reporting period for the 2014 PQRS incentive is the 12-month period from January 1 through December 31 of such program year.

(ii) [Reserved].

* * * * *

(e) * * *

(2) The Secretary shall treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (h) of this section), if the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry (as defined in paragraph (b) of this section).

(i) For purposes of this paragraph, the reporting period for the payment adjustment, with respect to a payment adjustment year, is the 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.

(ii) [Reserved].

(f) *Use of consensus-based quality measures for satisfactory reporting.* * * *

* * * * *

(4) These criteria do not apply to measures reported by qualified clinical data registries for purposes of satisfactory participation.

* * * * *

(g) *Satisfactory reporting requirements for the incentive payments.* * * *

* * * * *

(3) *Reporting mechanisms for group practices.* With the exception of a group practice (as defined in paragraph (b) of this section) who wishes to participate in the Physician Quality Reporting System using the certified survey vendor mechanism (as specified in paragraph (g)(3)(v) of this section), a group practice must report information on Physician Quality Reporting System quality measures identified by CMS in one of the following manners:

* * * * *

(v) *Certified survey vendors.* For 2014 and subsequent years, reporting CAHPS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional reporting mechanism in order to meet the criteria for satisfactory reporting for the incentive payments.

(h) Satisfactory reporting for the payment adjustments. * * *

* * * * *

(3) *Reporting mechanisms for group practices.* With the exception of a group practice (as defined in paragraph (b) of this section) who wishes to participate in the Physician Quality Reporting System using the certified survey vendor mechanism (as specified in paragraph (g)(3)(v) of this section), a group practice participating in the Physician Quality Reporting System must report information on Physician Quality Reporting System quality measures identified by CMS in one of the following manners:

* * * * *

(vi) Certified Survey Vendors. For 2014 and subsequent years, reporting CAHPS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional reporting mechanism in order to meet the criteria for satisfactory reporting for the payment adjustment.

* * * * *

(j) *Informal review.* Eligible professionals (or in the case of group practices defined in paragraph (b) of this section) may seek an informal review of the determination that an eligible professional (or in the case of group practices defined in paragraph (b) of this section) did not satisfactorily submit data on quality measures under the Physician Quality Reporting System or an eligible professional did not satisfactorily participate in a qualified clinical data registry under the Physician Quality Reporting System.

* * * * *

■ 28. Section 414.511 is added to subpart G to read as follows:

§ 414.511 Adjustments to the Clinical Laboratory Fee Schedule based on Technological Changes.

(a) CMS may make adjustments to the as CMS determines are justified by technological changes.

(b) Technological changes are changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used.

(c) CMS will propose and finalize any adjustments to the fee schedules as CMS determines are justified by technological changes in the **Federal Register**.

■ 29. Section 414.610 is amended by—

■ A. Revising paragraphs (c)(1)(ii) and (c)(5)(ii).

■ B. Adding paragraph (c)(8).

■ C. Revising paragraph (h).

The revisions and addition read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through December 31, 2013, ambulance services originating in:

(A) Urban areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section.

(B) Rural areas (both base rate and mileage) are paid based on a rate that is 3 percent higher than otherwise is applicable under this section.

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through December 31, 2013, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

* * * * *

(8) For ambulance services furnished on or after October 1, 2013 consisting of non-emergency basic life support (BLS)

services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B)) furnished other than on an emergency basis by a provider of services or a renal dialysis facility, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent.

* * * * *

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through June 30, 2013.

■ 30. Section 414.1210 is amended by revising paragraphs (a) and (c) to read as follows:

§ 414.1210 Application of the value-based payment modifier.

(a) The value-based payment modifier is applicable:

(1) For the CY 2015 payment adjustment period, to physicians in groups with 100 or more eligible professionals based on the performance period described at § 414.1215(a).

(2) For the CY 2016 payment adjustment period, to physicians in groups with 10 or more eligible professionals based on the performance period described at § 414.1215(b).

* * * * *

(c) *Group size determination.* The list of groups of physicians subject to the value-based payment modifier for the CY 2015 payment adjustment period is based on a query of PECOS on October 15, 2013. For each subsequent calendar year payment adjustment period, the list of groups of physicians subject to the value-based payment modifier is based on a query of PECOS that occurs within 10 days of the close of the PQRS group registration process during the applicable performance period described at § 414.1215. Groups of physicians are removed from the PECOS-generated list if, based on a claims analysis, the group of physicians did not have the required number of eligible professionals, as defined in § 414.1210(a), that submitted claims during the performance period for the applicable calendar year payment adjustment period.

■ 31. Section 414.1215 is amended by adding paragraph (c) to read as follows:

§ 414.1215 Performance and payment adjustment periods for the value-based payment modifier.

* * * * *

(c) The performance period is calendar year 2015 for value-based payment modifier adjustments made in the calendar year 2017 payment adjustment period.

■ 32. Section 414.1220 is revised to read as follows:

§ 414.1220 Reporting mechanisms for the value-based payment modifier.

Groups of physicians subject to the value-based payment modifier (or individual eligible professionals within such groups) may submit data on quality measures as specified under the Physician Quality Reporting System using the reporting mechanisms for which they are eligible.

■ 33. Section 414.1225 is revised to read as follows:

§ 414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.

All of the quality measures for which groups of physicians or individual eligible professionals are eligible to report under the Physician Quality Reporting System in a given calendar year are used to calculate the value-based payment modifier for the applicable payment adjustment period, as defined in § 414.1215, to the extent a group of physicians or individual eligible professionals within such group submits data on such measures.

■ 34. Section 414.1235 is revised to read as follows:

§ 414.1235 Cost measures.

(a) *Included measures.* Beginning with the CY 2016 payment adjustment period, costs for groups of physicians subject to the value-based payment modifier are assessed based on a cost composite comprised of the following 6 cost measures (only the measures identified in paragraphs (a)(1) through (5) of this section are included for the value-based payment modifier for the CY 2015 payment adjustment period):

(1) Total per capita costs for all attributed beneficiaries.

(2) Total per capita costs for all attributed beneficiaries with diabetes.

(3) Total per capita costs for all attributed beneficiaries with coronary artery disease.

(4) Total per capita costs for all attributed beneficiaries with chronic obstructive pulmonary disease.

(5) Total per capita costs for all attributed beneficiaries with heart failure.

(6) Medicare Spending per Beneficiary associated with an acute inpatient hospitalization.

(b) *Included payments.* Cost measures enumerated in paragraph (a) of this section include all fee-for-service payments made under Medicare Part A and Part B.

(c) *Cost measure adjustments.* (1) Payments under Medicare Part A and Part B will be adjusted using CMS' payment standardization methodology to ensure fair comparisons across geographic areas.

(2) The CMS–HCC model (and adjustments for ESRD status) is used to adjust standardized payments for the measures listed at paragraphs (a)(1) through (5) of this section.

(3) The beneficiary's age and severity of illness are used to adjust the Medicare Spending per Beneficiary measure as specified in paragraph (a)(6) of this section.

■ 35. Section 414.1240 is revised to read as follows:

§ 414.1240 Attribution for quality of care and cost measures.

(a) Beneficiaries are attributed to groups of physicians subject to the value-based payment modifier using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter, for measures other than the Medicare Spending per Beneficiary measure.

(b) For the Medicare Spending per Beneficiary (MSPB) measure, a MSPB episode is attributed to a group of physicians subject to the value-based payment modifier if any eligible professional in the group submits a Medicare Part B claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period described at § 414.1215.

■ 36. Section 414.1255 is revised to read as follows:

§ 414.1255 Benchmarks for cost measures.

(a) For the CY 2015 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated among all groups of physicians for which beneficiaries are attributed to the group of physicians that are subject to the value-based payment modifier. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of beneficiaries used to calculate the group of physician's performance rate.

(b) Beginning with the CY 2016 payment adjustment period, the cost

measures of a group of physicians subject to the value-based payment modifier are adjusted to account for the group's specialty mix, by computing the weighted average of the national specialty-specific expected costs. Each national specialty-specific expected cost is weighted by the proportion of each specialty in the group, the number of eligible professionals of each specialty in the group, and the number of beneficiaries attributed to the group.

(c) The national specialty-specific expected costs referenced in paragraph (b) of this section are derived by calculating, for each specialty, the average cost of beneficiaries attributed to groups of physicians that include that specialty.

■ 37. Section 414.1260 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 414.1260 Composite scores.

* * * * *

(b) * * *

(1) * * *

(i) Total per capita costs for all attributed beneficiaries: Total per capita costs measure and Medicare Spending per Beneficiary measure; and

* * * * *

■ 38. Section 414.1270 is revised to read as follows:

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

(a) For the CY 2015 payment adjustment period:

(1) *Downward payment adjustments.* A downward payment adjustment will be applied to a group of physicians subject to the value-based payment modifier if—

(i) Such group neither self-nominates for the PQRS GPRO and reports at least one measure, nor elects the PQRS administrative claims option for CY 2013 as defined in § 414.90(h).

(A) Such adjustment will be −1.0 percent.

(B) [Reserved].

(ii) Such group elects that its value-based payment modifier be calculated using a quality-tiering approach, and is determined to have poor performance (low quality and high costs; low quality and average costs; or average quality and high costs).

(A) Such adjustment will not exceed −1.0 percent as specified in § 414.1275(c)(1).

(B) [Reserved].

(2) *No payment adjustments.* There will be no value-based payment modifier adjustment applied to a group of physicians subject to the value-based payment modifier if such group either:

(i) Self-nominates for the PQRS GPRO and reports at least one measure; or

(ii) Elects the PQRS administrative claims option for CY 2013 as defined in § 414.90(h).

(3) *Upward payment adjustments.* If a group of physicians subject to the value-based payment modifier elects that the value-based payment modifier be calculated using a quality-tiering approach, upward payment adjustments are determined based on the projected aggregate amount of downward payment adjustments determined under paragraph (a)(1) of this section and applied as specified in § 414.1275(c)(1).

(b) For the CY 2016 payment adjustment period:

(1) A downward payment adjustment of −2.0 percent will be applied to a group of physicians subject to the value-based payment modifier if, during the applicable performance period as defined in § 414.1215, the following apply:

(i) Such group does not self-nominate for the PQRS GPRO and meet the criteria as a group to avoid the PQRS payment adjustment for CY 2016 as specified by CMS; and

(ii) Seventy percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2016 as specified by CMS.

(2) For a group of physicians comprised of 100 or more eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(2).

(3) For a group of physicians comprised of between 10 and 99 eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(2), except that such adjustment will be 0.0 percent if the group of physicians is determined to be low quality/high cost, low quality/average cost, or average quality/high cost.

(4) If all of the eligible professionals in a group of physicians subject to the value-based payment modifier participate as individuals in the PQRS using a qualified clinical data registry or any other reporting mechanism available to them, and CMS is unable to receive quality performance data for those eligible professionals under that reporting mechanism, the quality composite score for such group will be classified as ''average'' under § 414.1275(b)(1).

(5) A group of physicians subject to the value-based payment modifier will receive a cost composite score that is classified as ''average'' under § 414.1275(b)(2) if such group does not have at least one cost measure in its cost composite with at least 20 cases.

■ 39. Section 414.1275 is amended by revising paragraphs (a) and (c) and (d) introductory text to read as follows:

The revisions and additions read as follows:

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

(a) The value-based payment modifier amount for a group of physicians subject to the value-based payment modifier is based upon a comparison of the composite of quality of care measures and a composite of cost measures.

* * * * *

(c)(1) The following value-based payment modifier percentages apply to the CY 2015 payment adjustment period:

CY 2015 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost (percent)
High quality	+2.0x*	+1.0x*	+0.0
Average quality	+1.0x*	+0.0%	−0.5
Low quality	+0.0%	−0.5	−1.0

*Groups of physicians eligible for an additional +1.0x if (1) reporting Physician Quality Reporting System quality measures through the GPRO web-interface or CMS-qualified registry, and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

(2) The following value-based payment modifier percentages apply to the CY 2016 payment adjustment period:

CY 2016 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost (percent)
High quality	+2.0x*	+1.0x*	+0.0
Average quality	+1.0x*	+0.0%	−1.0
Low quality	+0.0%	−1.0%	−2.0

*Groups of physicians eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

(d) Groups of physicians subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2015 payment adjustment period elect the quality-tiering approach or for the CY 2016 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 40. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 41. Section 423.160 is amended by—

■ A. Revising paragraphs (b)(1)(i) through (iii).

■ B. Adding paragraphs (b)(1)(iv), (b)(5)(i) through (iii), and (c)(1)(vi).

The revisions and additions read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(i) Prior to April 1, 2009, the standards specified in paragraphs (b)(2)(i), (b)(3)–(b)(4), (b)(5)(i), and (b)(6).

(ii) On or after April 1, 2009, to [59 days after publication of the final rule], 2013, the standards specified in paragraphs (b)(2)(ii), (b)(3) through (b)(4), (b)(5)(i) and (b)(6).

(iii) From [60 days after publication of the final rule] until June 30, 2014 the standards specified in paragraphs (b)(2)(ii), (b)(3) and (4), (b)(5)(ii), and (b)(6).

(iv) From July 1, 2014, the standards specified in paragraphs (b)(2)(ii), (b)(3) through (b)(4), (b)(5)(iii) and (b)(6).

* * * * *

(5) * * *

(i) *Formulary and benefits.* Before The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(ii) *Formulary and benefits.* On The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section), or The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), January 2011(incorporated by reference in paragraph (c)(1)(vi) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(iii) Formulary and benefits. The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), January 2011 (incorporated by reference in paragraph (c)(1)(vi) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

* * * * *

(c) * * *

(1) * * *

(vi) The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), published January 2011.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 42. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 43. Section 425.308 is amended by revising paragraph (e) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(e) *Results of claims based measures.* Quality measures reported using a CMS web interface and patient experience of care survey measures will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

■ 44. Section 425.502 is amended by revising paragraph (b)(2) to read as follows:

§ 425.502 Calculating the ACO quality performance score.

* * * * *

(b) * * *

(2)(i) CMS will define the quality benchmarks using Medicare Advantage and fee-for-service Medicare data. When data are unavailable, inadequate, or unreliable to set the quality benchmarks, CMS will set the benchmarks using flat percentages.

(ii) CMS will reduce performance rate clustering in tightly clustered quality measures.

(A) A tightly clustered measure is defined as a measure where there is less than a 6.0 percentage point spread between the 30th and 90th deciles.

(B) For tightly clustered measures, CMS will apply a 1.0 fixed percentage point spread between each deciles, using the 60th percentile as the starting point.

(C) CMS does not apply the methodology in this paragraph (b)(2)(ii) to measures scored as ratios.

* * * * *

■ 45. Section 425.504 is amended by:

■ A. Revising the section heading.

■ B. Revising paragraphs (a)(1), (b) heading, and (b)(1).

■ C. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System Incentive and Payment Adjustment.

(a) * * *

(1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under § 425.500 using a CMS web interface, to qualify on behalf of their eligible professionals for the Physician Quality Reporting System

incentive under the Shared Savings Program.

* * * * *

(b) *Physician Quality Reporting System payment adjustment for 2015.* (1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit one of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the 2015 Physician Quality Reporting System payment adjustment under the Shared Savings Program.

* * * * *

(c) Physician Quality Reporting System payment adjustment for 2016 and subsequent years.

(1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit one of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.

(2)(i) ACO providers/suppliers that are eligible professionals within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.

(ii) ACOs, on behalf of its ACO provider/suppliers who are eligible professionals, must satisfactorily report all of the ACO GPRO measures determined under § 425.500 using a CMS web interface for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.

(3) If an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, does not satisfactorily report for purposes of the Physician Quality Reporting System payment adjustment for 2016 and subsequent years, each ACO supplier/provider who is an eligible professional, will receive a payment adjustment, as described in § 414.90(e).

(4) ACO participant TINs and individual ACO providers/suppliers billing through an ACO participant TIN who are eligible professionals cannot satisfactorily report for purposes of a Physician Quality Reporting System payment adjustment outside of the Medicare Shared Savings Program for 2016 and subsequent years.

(5) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program for 2016 and subsequent years, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act, as described in § 414.90(e).

(d) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 20, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 26, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–16547 Filed 7–8–13; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 78 Friday,
No. 139 July 19, 2013

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, et al.

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, 416, 419, 475, 476, 486, and 495

[CMS–1601–P]

RIN 0938–AR54

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2014 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Hospital Value-Based Purchasing (VBP) Program.

We are proposing changes to the conditions for coverage (CfCs) for organ procurement organizations (OPOs); revisions to the Quality Improvement Organization (QIO) regulations; changes to the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program; and changes relating to provider reimbursement determinations and appeals.

DATES: *Comment Period:* To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 6, 2013.

ADDRESSES: In commenting, please refer to file code CMS–1601–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1601–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1601–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION, CONTACT:

Marjorie Baldo, (401) 786–4617, for issues related to new CPT and Level II HCPCS codes, exceptions to the 2 times rule, and stereotactic radiosurgery services.

Anita Bhatia, (410) 786–7236, for issues related to the Ambulatory Surgical Center Quality Reporting (ASCQR) Program—Program Administration and Reconsideration Issues.

Chuck Braver, (410) 786–9379, for issues related to the Advisory Panel on Hospital Outpatient Payment (HOP Panel).

Erick Chuang, (410) 786–1816, for issues related to OPPS APC weights, mean calculation, copayments, wage index, outlier payments, cost-to-charge ratios (CCRs), and rural hospital payments.

Diane Corning, (410) 786–8486, for issues related to the Conditions for Coverage for Organ Procurement Organizations (OPOs).

Dexter Dickey, (410) 786–6856, or Dorothy Myrick, (410) 786–9671, for issues related to partial hospitalization and community mental health center (CMHC) issues.

Roxanne Dupert-Frank, (410) 786–4827, for issues related to the Hospital Value-Based Purchasing (VBP) Program.

Dan Duvall, (410) 786–4592, for issues related to comprehensive APCs.

Shaheen Halim (410) 786–0641, for issues related to the Hospital Outpatient Quality Reporting Program (OQR)—Measures Issues and Publication of Hospital OQR Program Data, and Ambulatory Surgical Center Quality Reporting (ASCQR) Program—Measures Issues and Publication of ASCQR Program Data.

James Hart, (410) 786–9520, for issues related to the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program.

Jeneen Iwugo, (410) 786–1028, for issues related to the revisions of the Quality Improvement Organization (QIO) Regulations.

Twi Jackson, (410) 786–1159, for issues related to blood products, device-dependent APCs, extended assessment and management composite APCs, hospital outpatient visits, inpatient-only procedures, and no cost/full credit and partial credit devices.

Marina Kushnirova, (410) 786–2682, for issues related to OPPS status indicators and comment indicators.

Barry Levi, (410) 786–4529, for issues related to OPPS pass-through devices, brachytherapy sources, intraoperative

radiation therapy (IORT), brachytherapy composite APC, multiple imaging composite APCs, and cardiac electrophysiologic evaluation and ablation composite APC.

Ann Marshall, (410) 786–3059, for issues related to packaged items/services, hospital outpatient supervision, proton beam therapy, therapy caps in CAHs, incident to physician or nonphysician practitioner services, and provider-based issues.

Danielle Moskos, (410) 786–8866, or Michael Zleit, (410) 786–2050, for issues related to Provider Reimbursement Determination Appeals.

James Poyer, (410) 786–2261, for issues related to the Hospital Outpatient Quality Reporting—Program Administration, Validation, and Reconsideration Issues.

Char Thompson, (410) 786–2300, for issues related to OPPS drugs, radiopharmaceuticals, biologicals, blood clotting factors, new technology intraocular lenses (NTIOLs), and ambulatory surgical center (ASC) payments.

Marjorie Baldo, (410) 786–4617, for all other issues related to hospital outpatient and ambulatory surgical center payments not previously identified.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/*.

Addenda Available Only Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda will be published and available only on the CMS Web site. The Addenda relating to the OPPS are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The Addenda relating to the ASC payment system are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html*.

Alphabetical List of Acronyms Appearing in This Federal Register Document

AHA American Hospital Association
AMA American Medical Association
APC Ambulatory Payment Classification
ASC Ambulatory surgical center
ASCQR Ambulatory Surgical Center Quality Reporting
ASP Average sales price
AWP Average wholesale price
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CAH Critical access hospital
CAP Competitive Acquisition Program
CASPER Certification and Survey Provider Enhanced Reporting
CAUTI Catheter associated urinary tract infection
CBSA Core-Based Statistical Area
CCI Correct Coding Initiative
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDC Centers for Disease Control and Prevention
CEO Chief executive officer
CERT Comprehensive Error Rate Testing
CfC [Medicare] Condition for coverage
CFR Code of Federal Regulations
CLFS Clinical Laboratory Fee Schedule
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
CoP [Medicare] Condition of participation
CPI–U Consumer Price Index for All Urban Consumers
CPT Current Procedural Terminology (copyrighted by the American Medical Association)
CQM Clinical quality measure
CR Change request
CSAC Consensus Standards Approval Committee
CY Calendar year
DFO Designated Federal Official
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-Related Group
DSH Disproportionate share hospital
EACH Essential access community hospital
eCQM Electronically specified clinical quality measure
ECT Electroconvulsive therapy
ED Emergency department
E/M Evaluation and management
EHR Electronic health record
ESRD End-stage renal disease
FACA Federal Advisory Committee Act, Public Law 92–463
FDA Food and Drug Administration
FFS [Medicare] Fee-for-service
FY Fiscal year
FFY Federal fiscal year
GAO Government Accountability Office
HAI Healthcare-associated infection
HCERA Health Care and Education Reconciliation Act of 2010, Public Law 111–152
HCPCS Healthcare Common Procedure Coding System
HCRIS Hospital Cost Report Information System
HEU Highly enriched uranium
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HITECH Health Information Technology for Economic and Clinical Health [Act] (found in the American Recovery and Reinvestment Act of 2009, Pub. L. 111–5)
HOP Hospital Outpatient Payment [Panel]
HOPD Hospital outpatient department
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD Implantable cardioverter defibrillator
ICU Intensive care unit
IHS Indian Health Service
IMRT Intensity Modulated Radiation Therapy
I/OCE Integrated Outpatient Code Editor
IOL Intraocular lens
IOM Institute of Medicine
IORT Intraoperative radiation treatment
IPPS [Hospital] Inpatient Prospective Payment System
IQR [Hospital] Inpatient Quality Reporting
LDR Low dose rate
LOS Length of Stay
LTCH Long-term care hospital
MAC Medicare Administrative Contractor
MAP Measure Application Partnership
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multifactor productivity
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act under Division B, Title I of

the Tax Relief Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MPFS Medicare Physician Fee Schedule
MRA Magnetic resonance angiography
MRI Magnetic resonance imaging
MSA Metropolitan Statistical Area
NCCI National Correct Coding Initiative
NHSN National Healthcare Safety Network
NQF National Quality Forum
NTIOL New technology intraocular lens
NUBC National Uniform Billing Committee
OACT [CMS] Office of the Actuary
OBRA Omnibus Budget Reconciliation Act of 1996, Public Law 99–509
OIG [HHS] Office of the Inspector General
OMB Office of Management and Budget
OPD [Hospital] Outpatient Department
OPPS [Hospital] Outpatient Prospective Payment System
OPSF Outpatient Provider-Specific File
OQR [Hospital] Outpatient Quality Reporting
OT Occupational therapy
PBD Provider-Based Department
PCR Payment-to-cost ratio
PE Practice expense
PEPPER Program for Evaluating Payment Patterns Electronic Report
PHP Partial hospitalization program
PHS Public Health Service [Act], Public Law 96–88
PPI Producer Price Index
PPS Prospective payment system
PQRS Physician Quality Reporting System
PT Physical therapy
QDC Quality data code
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RTI Research Triangle Institute, International
RVU Relative value unit
SCH Sole community hospital
SCOD Specified covered outpatient drugs
SI Status indicator
SIR Standardized infection ratio
SLP Speech-language pathology
SNF Skilled Nursing Facility
SRS Stereotactic Radiosurgery
TEP Technical Expert Panel
TMS Transcranial Magnetic Stimulation Therapy
TOPs Transitional Outpatient Payments
UR Utilization review
USPSTF United States Preventive Services Task Force
UTI Urinary tract infection
VBP Value-based purchasing
WAC Wholesale acquisition cost

Table of Contents

I. Summary and Background

A. Executive Summary of This Proposed Rule

1. Purpose

In this proposed rule, we are proposing to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments and Ambulatory Surgical Centers (ASCs) beginning January 1, 2014. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the relative payment weights and the conversion factor for services payable under the Outpatient Prospective Payment System (OPPS). Under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, we are proposing to update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Hospital Value-Based Purchasing (VBP) Program.

We are proposing changes to the conditions for coverage (CfCs) for organ procurement organizations (OPOs); revisions to the Quality Improvement Organization (QIO) regulations; changes to the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program; and changes relating to provider reimbursement determinations and appeals.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2013, we are proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.8 percent. This proposed increase is based on the proposed hospital inpatient market basket percentage increase of 2.5 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.4 percentage points, and minus a 0.3 percentage point adjustment required by the Affordable Care Act. Under this proposed rule, we estimate that proposed total payments for CY 2014, including beneficiary cost-sharing, to the almost 4,000 facilities paid under the OPPS (including general

acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), will be approximately $50.4 billion, an increase of approximately $4.4 billion compared to CY 2013 payments, or $600 million excluding our estimated changes in enrollment, utilization, and case-mix

We are proposing to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

• *Rural Adjustment:* We are proposing to continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This adjustment will apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost.

• *Cancer Hospital Payment Adjustment:* For CY 2014, we are proposing to continue our policy to provide additional payments to cancer hospitals so that the hospital's payment-to-cost ratio (PCR) with the payment adjustment is equal to the weighted average PCR for the other OPPS hospitals using the most recent submitted or settled cost report data. Based on those data, a target PCR of 0.90 will be used to determine the proposed CY 2014 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment amount associated with the cancer hospital payment adjustment will be the additional payment needed to result in a PCR equal to 0.90 for each cancer hospital.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals:* For CY 2014, proposed payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status would be set at the statutory default of average sales price (ASP) plus 6 percent.

• *Packaging Proposals:* The OPPS packages payment for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. For 2014, we are proposing to unconditionally package or conditionally package the following items and services and to add them to the list of OPPS packaged items and services in 42 CFR 419.2(b):

(1) Drugs, biologicals, and radiopharmaceuticals that function as supplies in a diagnostic test or procedure;

(2) Drugs and biologicals that function as supplies or devices in a surgical procedure;

(3) Laboratory tests;

(4) Procedures described by add-on codes;

(5) Ancillary services (status indicator ''X'');

(6) Diagnostic tests on the bypass list; and

(7) Device removal procedures.

We refer readers to section II.A.3. of this proposed rule for a complete description of our 2014 packaging proposals.

• *Establishing Comprehensive APCs:* In order to improve the accuracy and transparency of our payment for certain device-dependent services, for CY 2014, we are proposing to create 29 comprehensive APCs to prospectively pay for the most costly device-dependent services. We are proposing to define a comprehensive APC as a classification for the provision of a primary service and all adjunct services provided to support the delivery of the primary service. The comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, resulting in a single prospective payment based on the cost of all individually reported codes that represent the delivery of a primary service as well as all adjunct services provided to support that delivery. We are proposing to make a single payment for the comprehensive service based on all charges on the claim, excluding only charges for services that cannot be covered by Medicare Part B or that are not payable under the OPPS.

• *Payment of Hospital Outpatient Visits:* For CY 2014 we are proposing to replace the current five levels of visit codes for each clinic, Type A ED, and Type B ED visits with three new alphanumeric Level II HCPCS codes representing a single level of payment for the three types of visits, respectively. We are proposing to assign the new alphanumeric Level II HCPCS to newly created APCs with CY 2014 OPPS payment rates based on the total mean costs of Level 1 through Level 5 visit codes obtained from CY 2012 OPPS claims data for each visit type.

• *Proposed OPPS Nonrecurring Policy Changes:* We note in this proposed rule that we expect to allow the enforcement instruction for the supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals to expire at the end of CY 2013. In addition, we are proposing to amend the conditions of payment for ''incident to'' hospital or CAH outpatient services (sometimes referred to as hospital or CAH ''therapeutic'' services) to require that individuals furnishing these services be in compliance with State law. We are soliciting public comments regarding a potential new claims or other data element that would indicate that the services were furnished in an off-campus provider-based department. Finally, we refer readers to the CY 2014 Medicare Physician Fee Schedule (MPFS) proposed rule (CMS–1600–P) to review Medicare's proposal to apply the therapy caps and related provisions under section 1833(g) of the Act to physical therapy (PT), speech-language pathology (SLP) and occupational therapy (OT) (''therapy'') services that are furnished by a CAH, effective January 1, 2014.

• *Ambulatory Surgical Center Payment Update:* For CY 2014, we are proposing to increase payment rates under the ASC payment system by 0.9 percent. This proposed increase is based on a projected CPI–U update of 1.4 percent minus a multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.5 percent. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2014 would be approximately $3.980 billion, an increase of approximately $133 million compared to estimated CY 2013 payments.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are proposing five quality measures for the CY 2016 and subsequent years payment determinations: four where aggregate data (numerators, denominators, and exclusions) are collected and data submitted via an online Web-based tool located on a CMS Web page and one HAI measure submitted through the CDC's NHSN. We also are proposing to remove two measures and are proposing to codify administrative procedures.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are proposing four quality measures for the CY 2016 and subsequent years payment determinations where data collection would begin in CY 2014. We are proposing to collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these

four proposed chart-abstracted measures via an online Web-based tool located on a CMS Web page. We also are proposing, for the CY 2016 payment determination and subsequent years' payment determinations, requirements for facility participation, data collection, and submission for claims-based, CMS Web-based, and NHSN measures.

• *Proposed Revisions to the Quality Improvement Organizations Regulations.* We are proposing to update the regulations at 42 CFR parts 475 and 476 based on the recently enacted Trade Adjustment Assistance Extension Act of 2011 (TAAEA) (Pub. L. 112–40, Section 261) where by Congress authorized numerous changes to the original legislation and included additional flexibility for the Secretary in the administration of the QIO program. Currently, 42 CFR Part 475 includes definitions and standards governing eligibility and the award of contracts to QIOs. In this proposed rule, we set forth proposals for the partial deletion and revision of the regulations under 42 CFR Parts 475 and 476, which relate to the QIO program, including the following: (1) Replace nomenclature in Part 475 and 476 that has been amended by the TAAEA; (2) revise the existing definition for the term ''physician''; (3) add new definitions as necessary to support the new substantive provisions in Subpart C; and (4) replace some of the substantive provisions in Subpart C in their entirety to fully exercise the Secretary's authority for the program and update the contracting requirements to align with contemporary quality improvement.

• *Proposed Changes to the Medicare Fee-for-Service Electronic Record (EHR) Incentive Program.* We are proposing to the regulations to provide a special method for making hospital-based determinations for 2013 only in the cases of those eligible professionals (EPs) who reassign their benefits to Method II CAHs. We have been unable to make EHR payments to these EPs for their CAH II claims, or to take those claims into consideration in making hospital-based determinations because of systems limitations. Adopting our proposed method for 2013 will allow us to begin making payments based on CAH II one year earlier than we would be able to do under current regulations. We also are proposing a minor clarification to the regulations concerning the cost reporting period to be used in determining final EHR payments for hospitals.

3. Summary of Costs and Benefits

In sections XXIII. and XXIV. of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the proposed changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the OPPS Update

(1) Impacts of All Proposed OPPS Changes

Table 39 in section XXIII. of this proposed rule displays the distributional impact all the proposed OPPS changes on various groups of hospitals and CMHCs for CY 2014 compared to all estimated OPPS payments in CY 2013. We estimate that the proposed policies in this proposed rule would result in a 1.8 percent overall increase in OPPS payments to providers. We estimate that the proposed increase in OPPS expenditures, including beneficiary cost-sharing, would be approximately $600 million, not taking into account potential changes in enrollment, utilization, and case-mix. Taking into account estimated spending changes that are attributable to these factors, we estimate an increase of approximately $4.372 billion in OPPS expenditures, including beneficiary cost-sharing, for CY 2014 compared to CY 2013 OPPS expenditures. We estimate that proposed total OPPS payments, including beneficiary cost-sharing, would be $50.4 billion for CY 2014.

We estimated the isolated impact of our proposed OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure that we adopted for CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a 3.8 percent decrease in CY 2014 payments to CMHCs relative to their CY 2013 payments.

(2) Impacts of the Proposed Updated Wage Indices

We estimate no significant impacts related to our proposal to update the wage indices and apply the frontier State wage index. Proposed adjustments to the wage indices other than the frontier State wage adjustment would not significantly affect most hospitals.

(3) Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our proposed CY 2014 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural and cancer hospital payment adjustments, and the proposed adjustment amounts do not significantly impact the budget neutrality adjustments for these proposed policies.

(4) Impacts of the Proposed OPD Fee Schedule Increase Factor

We estimate that, for many hospitals, the application of the proposed OPD fee schedule increase factor of 1.8 percent to the conversion factor for CY 2014 would mitigate the small negative impacts of the budget neutrality adjustments. While most classes of hospitals would receive an increase that is in line with the proposed 1.8 percent overall increase after the update is applied to the budget neutrality adjustments, some hospitals would receive smaller but still generally positive overall increases.

b. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The proposed percentage change in estimated total payments by specialty groups under the CY 2014 payment rates compared to estimated CY 2013 payment rates ranges between −12 percent for ancillary items and services and 17 percent for hemic and lymphatic system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our proposed CY 2014 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the ASCQR Program

We do not expect our proposed CY 2014 proposed policies to significantly affect the number of ASCs that do not receive a full annual payment update beginning in CY 2015.

e. Impacts for the Proposed QIO Program Changes

We estimate the effects of the proposed QIO Program changes to be consistent with the Congressional Budget Office's 2011 Cost Estimate of the Trade Bill (H.R. 2832) which included a reduction in spending of $330 million over the 2012–2021 period. According to the CBO Estimate the Act and subsequently the proposed regulatory changes ''would modify the provisions under which CMS contracts with independent entities called ['']Quality Improvement Organizations [(QIOs)''] in Medicare. QIOs, generally staffed by health care professionals, review medical care, help beneficiaries with complaints about the quality of

care, and implement care improvements. H.R. 2832 would make several changes to the composition and operation of QIOs, and would harmonize QIO contracts with requirements of the Federal Acquisition Regulation. Among those changes are a modification to expand the geographic scope of QIO contracts and a lengthening of the contract period. CBO estimates that those provisions would reduce spending by $330 million over the 2012–2021 period.''

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR Parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (These two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; and most recently the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; and most recently the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013.

Under the OPPS, we pay for hospital outpatient services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary originally exercised the authority granted under the statute to also exclude from the OPPS those services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the MPFS; laboratory services paid at the Clinical Laboratory Fee Schedule (CLFS) rates; services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22. This proposed rule includes proposals to modify 42 CFR 419.22 and include in the OPPS some of these currently excluded services.

Under § 419.20(b) of the regulations, we specify the types of hospitals and entities that are excluded from payment under the OPPS. These excluded entities include: Maryland hospitals, but

only for services that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act; CAHs; hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel), Formerly Named the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act and section 222 of the Public Health Service (PHS) Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the PHS Act which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel, or the Panel). The Panel is not restricted to using data compiled by CMS, and in conducting its review it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the HOP Panel, at that time named the APC Panel. This expert panel, which may be composed of up to 19 appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise), reviews clinical data and advises CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that: the Panel continues to be technical in nature; is governed by the provisions of the FACA; may convene up to three meetings per year; has a Designated Federal Official (DFO); and is chaired by a Federal Official designated by the Secretary. The current charter was amended on November 15, 2011 and the Panel was renamed to reflect expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and therefore to add CAHs to its membership.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.*

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on March 11, 2013. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership and to announce new members.

The Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required review process. The three current subcommittees are the Data Subcommittee, the Visits and Observation Subcommittee, and the Subcommittee for APC Groups and Status Indicator (SI) Assignments.

The Data Subcommittee is responsible for studying the data issues confronting the Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS (for example, APC configurations and APC relative payment weights). The Subcommittee for APC Groups and SI Assignments advises the Panel on the following issues: the appropriate SIs to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid; and the appropriate APC placement of HCPCS codes regarding services for which separate payment is made.

Each of these subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended that the subcommittees continue at the August 2013 Panel meeting. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the March 2013 Panel meeting are included in the sections of this final rule that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at: *http://fido.gov/facadatabase/public.asp.*

F. Public Comments Received on the CY 2013 OPPS/ASC Final Rule With Comment Period

We received approximately 27 timely pieces of correspondence on the CY 2013 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 15, 2012 (77 FR 68210), some of which contained comments on the interim APC assignments and/or status indicators of HCPCS codes identified with comment indicator ''NI'' in Addenda B, AA, and BB to that final rule. Summaries of these public comments on topics that were open to comment and our responses to them will be set forth in various sections of the final rule with comment period under the appropriate subject-matter headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2014 OPPS, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2014, and before January 1, 2015 (CY 2014), using the same basic methodology that we described in the CY 2013 OPPS/ASC final rule with comment period. That is, we are proposing to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights. Therefore, for the purpose of recalibrating the proposed APC relative payment weights for CY 2014, we used approximately 146 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for hospital outpatient department services furnished on or after January 1, 2012, and before January 1, 2013. For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Of the approximately 146 million final action claims for services provided in hospital outpatient settings used to calculate the CY 2014 OPPS payment rates for this proposed rule, approximately 117 million claims were the type of bill potentially appropriate for use in setting rates for OPPS services (but did not necessarily contain services payable under the OPPS). Of the approximately 117 million claims, approximately 5 million claims were not for services paid under the OPPS or were excluded as not appropriate for use (for example, erroneous cost-to-charge ratios (CCRs) or no HCPCS codes reported on the claim). From the remaining approximately 112 million claims, we created approximately 82 million single records, of which approximately 34 million were ''pseudo'' single or ''single session'' claims (created from approximately 19 million multiple procedure claims using the process we discuss later in this section). Approximately 1 million claims were trimmed out on cost or units in excess of +/− 3 standard deviations from the geometric mean, yielding approximately 82 million single bills for ratesetting. As described in section II.A.2. of this proposed rule, our data development process is designed with the goal of using appropriate cost information in setting the APC relative payment weights. The bypass process is described in section II.A.1.b. of this proposed rule. This section discusses how we develop ''pseudo'' single procedure claims (as defined below), with the intention of using more appropriate data from the available claims. In some cases, the bypass process allows us to use some portion of the submitted claim for cost estimation purposes, while the remaining information on the claim continues to be unusable. Consistent with the goal of using appropriate information in our data development process, we only use claims (or portions of each claim) that are appropriate for ratesetting purposes.

The proposed APC relative weights and payments for CY 2014 in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) were calculated using claims from CY 2012 that were processed through December 31, 2012. While prior to CY 2013 we historically based the payments on median hospital costs for services in the APC groups, beginning with the CY 2013 OPPS, we established the cost-based relative payment weights for the OPPS using geometric mean costs, as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271). For the CY 2014 OPPS, we are proposing to use this same methodology, basing payments on geometric mean costs. Under this methodology, we select claims for services paid under the OPPS and match these claims to the most recent cost report filed by the individual hospitals represented in our claims data. We continue to believe that it is appropriate to use the most current full calendar year claims data and the most recently submitted cost reports to calculate the relative costs underpinning the APC relative payment weights and the CY 2014 payment rates.

b. Proposed Use of Single and Multiple Procedure Claims

For CY 2014, in general, we are proposing to continue to use single procedure claims to set the costs on which the APC relative payment weights are based. We generally use single procedure claims to set the estimated costs for APCs because we believe that the OPPS relative weights on which payment rates are based should be derived from the costs of furnishing one unit of one procedure and because, in many circumstances, we are unable to ensure that packaged costs can be appropriately allocated across multiple procedures performed on the same date of service.

It is generally desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those claims for multiple procedures. As we have for several years, we are proposing to continue to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims. Through bypassing specified codes that we believe do not have significant packaged costs, we are able to use more data from multiple procedure claims. In many cases, this enables us to create multiple ''pseudo'' single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as ''pseudo'' single procedure claims. The history of our use of a bypass list to generate ''pseudo'' single procedure claims is well documented, most recently in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68227 through 68229). In addition, for CY 2008 (72 FR 66614 through 66664), we increased packaging and created the first composite APCs, and continued those policies through CY 2013. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for ratesetting by enabling us to use claims that contained multiple major procedures that previously would not have been usable. Further, for CY 2009, we expanded the composite APC model to one additional clinical area, multiple imaging services (73 FR 68559 through 68569), which also increased the number of bills we were able to use in developing the OPPS relative weights on which payments are based. We have continued the composite APCs for

multiple imaging services through CY 2013, and are proposing to continue this policy for CY 2014. We also are proposing to further expand our packaging policies for CY 2014. We refer readers to section II.A.2.f. of this proposed rule for a discussion of the use of claims in modeling the costs for composite APCs and to section II.A.3. of this proposed rule for a discussion of our proposed packaging policies for CY 2014.

We are proposing to continue to apply these processes to enable us to use as much claims data as possible for ratesetting for the CY 2014 OPPS. This methodology enabled us to create, for this proposed rule, approximately 34 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.f.(5) of this proposed rule for further discussion), to add to the approximately 48 million ''natural'' single procedure claims.

For CY 2014, we are proposing to bypass 179 HCPCS codes that are identified in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site). Since the inception of the bypass list, which is the list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims, we have calculated the percent of ''natural'' single bills that contained packaging for each HCPCS code and the amount of packaging on each ''natural'' single bill for each code. Each year, we generally retain the codes on the previous year's bypass list and use the updated year's data (for CY 2014, data available for the March 11, 2013 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2012 claims processed through September 30, 2012, and CY 2011 claims data processed through June 30, 2012, used to model the payment rates for CY 2013) to determine whether it would be appropriate to add additional codes to the previous year's bypass list. For CY 2014, we are proposing to continue to bypass all of the HCPCS codes on the CY 2013 OPPS bypass list, with the exception of HCPCS codes that we are proposing to delete for CY 2014, which are listed in Table 1 of this proposed rule. We also are proposing to remove HCPCS codes that are not separately paid under the OPPS because the purpose of the bypass list is to obtain more data for those codes relevant to ratesetting. Some of the codes we are proposing to remove from the CY 2014 bypass list are affected by the CY 2014 packaging proposal, discussed in section II.A.3. of this proposed rule. In addition, we are proposing to add to the bypass list for CY 2014 HCPCS codes not on the CY 2013 bypass list that, using either the CY 2013 final rule data (CY 2011 claims) or the March 11, 2013 Panel data (first 9 months of CY 2012 claims), met the empirical criteria for the bypass list that are summarized below. Finally, to remain consistent with the CY 2014 proposal to continue to develop OPPS relative payment weights based on geometric mean costs, we also are proposing that the packaged cost criterion continue to be based on the geometric mean cost. The entire list proposed for CY 2014 (including the codes that remain on the bypass list from prior years) is open to public comment. Because we must make some assumptions about packaging in the multiple procedure claims in order to assess a HCPCS code for addition to the bypass list, we assumed that the representation of packaging on ''natural'' single procedure claims for any given code is comparable to packaging for that code in the multiple procedure claims. The proposed criteria for the bypass list are:

- There are 100 or more ''natural'' single procedure claims for the code. This number of single procedure claims ensures that observed outcomes are sufficiently representative of packaging that might occur in the multiple claims.
- Five percent or fewer of the ''natural'' single procedure claims for the code have packaged costs on that single procedure claim for the code. This criterion results in limiting the amount of packaging being redistributed to the separately payable procedures remaining on the claim after the bypass code is removed and ensures that the costs associated with the bypass code represent the cost of the bypassed service.
- The geometric mean cost of packaging observed in the ''natural'' single procedure claims is equal to or less than $55. This criterion also limits the amount of error in redistributed costs. During the assessment of claims against the bypass criteria, we do not know the dollar value of the packaged cost that should be appropriately attributed to the other procedures on the claim. Therefore, ensuring that redistributed costs associated with a bypass code are small in amount and volume protects the validity of cost estimates for low cost services billed with the bypassed service.

We note that, as we did for CY 2013, we are proposing to continue to establish the CY 2014 OPPS relative payment weights based on geometric mean costs. To remain consistent in the metric used for identifying cost patterns, we are proposing to use the geometric mean cost of packaging to identify potential codes to add to the bypass list.

In response to public comments on the CY 2010 OPPS/ASC proposed rule requesting that the packaged cost threshold be updated, we considered whether it would be appropriate to update the $50 packaged cost threshold for inflation when examining potential bypass list additions. As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60328), the real value of this packaged cost threshold criterion has declined due to inflation, making the packaged cost threshold more restrictive over time when considering additions to the bypass list. Therefore, adjusting the threshold by the market basket increase would prevent continuing decline in the threshold's real value. Based on the same rationale described for the CY 2013 OPPS/ASC final rule with comment period (77 FR 68221), we are proposing for CY 2014 to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2013 market basket increase of 1.8 percent to the prior nonrounded dollar threshold of $53.76 (77 FR 68221), we determined that the threshold would remain for CY 2014 at $55 ($54.73 rounded to $55, the nearest $5 increment). Therefore, we are proposing to set the geometric mean packaged cost threshold on the CY 2012 claims at $55 for a code to be considered for addition to the CY 2014 OPPS bypass list.

- The code is not a code for an unlisted service. Unlisted codes do not describe a specific service, and thus their costs would not be appropriate for bypass list purposes.

In addition, we are proposing to continue to include on the bypass list HCPCS codes that CMS medical advisors believe have minimal associated packaging based on their clinical assessment of the complete CY 2014 OPPS proposal. Some of these codes were identified by CMS medical advisors and some were identified in prior years by commenters with specialized knowledge of the packaging associated with specific services. We also are proposing to continue to include certain HCPCS codes on the bypass list in order to purposefully direct the assignment of packaged costs to a companion code where services always appear together and where there would otherwise be few single procedure claims available for ratesetting. For example, we have previously discussed our reasoning for adding HCPCS code G0390 (Trauma response team associated with hospital

critical care service) to the bypass list (73 FR 68513).

As a result of the multiple imaging composite APCs that we established in CY 2009, the program logic for creating ''pseudo'' single procedure claims from bypassed codes that are also members of multiple imaging composite APCs changed. When creating the set of ''pseudo'' single procedure claims, claims that contain ''overlap bypass codes'' (those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs) were identified first. These HCPCS codes were then processed to create multiple imaging composite ''single session'' bills, that is, claims containing HCPCS codes from only one imaging family, thus suppressing the initial use of these codes as bypass codes. However, these ''overlap bypass codes'' were retained on the bypass list because, at the end of the ''pseudo'' single processing logic, we reassessed the claims without suppression of the ''overlap bypass codes'' under our longstanding ''pseudo'' single process to determine whether we could convert additional claims to ''pseudo'' single procedure claims. (We refer readers to section II.A.2.b. of this proposed rule for further discussion of the treatment of ''overlap bypass codes.'') This process also created multiple imaging composite ''single session'' bills that could be used for calculating composite APC costs. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site).

Addendum N to this proposed rule includes the proposed list of bypass codes for CY 2014. The list of bypass codes contains codes that were reported on claims for services in CY 2012 and, therefore, includes codes that were in effect in 2012 and used for billing but were deleted for CY 2013. We retained these deleted bypass codes on the proposed CY 2014 bypass list because these codes existed in CY 2012 and were covered OPD services in that period, and CY 2012 claims data are used to calculate CY 2014 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that were members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2014 are identified by asterisks (*) in the fourth column of Addendum N.

Table 1 below contains the list of codes that we are proposing to remove from the CY 2014 bypass list because these codes were either deleted from the HCPCS before CY 2012 (and therefore were not covered OPD services in CY 2012) or were not separately payable codes under the proposed CY 2014 OPPS because these codes are not used for ratesetting through the bypass process. The list of codes proposed for removal from the bypass list includes those that would be affected by the CY 2014 OPPS proposed packaging policy described in section II.A.3. of this proposed rule.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2014 BYPASS LIST

HCPCS Code	HCPCS Short descriptor
17003	Destruct premalg les 2–14.
31231	Nasal endoscopy dx.
31505	Diagnostic laryngoscopy.
31579	Diagnostic laryngoscopy.
51741	Electro-uroflowmetry first.
51798	Us urine capacity measure.
54240	Penis study.
56820	Exam of vulva w/scope.
57452	Exam of cervix w/scope.
57454	Bx/curett of cervix w/scope.
69210	Remove impacted ear wax.
70030	X-ray eye for foreign body.
70100	X-ray exam of jaw <4 views.
70110	X-ray exam of jaw 4/> views.
70120	X-ray exam of mastoids.
70130	X-ray exam of mastoids.
70140	X-ray exam of facial bones.
70150	X-ray exam of facial bones.
70160	X-ray exam of nasal bones.
70200	X-ray exam of eye sockets.
70210	X-ray exam of sinuses.
70220	X-ray exam of sinuses.
70240	X-ray exam pituitary saddle.
70250	X-ray exam of skull.
70260	X-ray exam of skull.
70320	Full mouth x-ray of teeth.
70328	X-ray exam of jaw joint.
70330	X-ray exam of jaw joints.
70355	Panoramic x-ray of jaws.
70360	X-ray exam of neck.
70370	Throat x-ray & fluoroscopy.
70371	Speech evaluation complex.
71021	Chest x-ray frnt lat lordotc.
71022	Chest x-ray frnt lat oblique.
71023	Chest x-ray and fluoroscopy.
71030	Chest x-ray 4/> views.
71034	Chest x-ray&fluoro 4/> views.
71035	Chest x-ray special views.
71100	X-ray exam ribs uni 2 views.
71101	X-ray exam unilat ribs/chest.
71110	X-ray exam ribs bil 3 views.
71111	X-ray exam ribs/chest 4/> vws.
71120	X-ray exam breastbone 2/>vws.
71130	X-ray strenoclavic jt 3/>vws.
72010	X-ray exam spine ap&lat.
72020	X-ray exam of spine 1 view.
72040	X-ray exam neck spine 3/<vws.
72050	X-ray exam neck spine 4/5vws.
72052	X-ray exam neck spine 6/>vws.
72069	X-ray exam trunk spine stand.
72070	X-ray exam thorac spine 2vws.
72072	X-ray exam thorac spine 3vws.
72074	X-ray exam thorac spine 4/>vw.
72080	X-ray exam trunk spine 2 vws.
72090	X-ray exam scloiosis erect.
72100	X-ray exam l-s spine ⅔ vws.
72110	X-ray exam l-2 spine 4/>vws.
72114	X-ray exam l-s spine bending.
72120	X-ray bend only l-s spine.
72170	X-ray exam of pelvis.
72190	X-ray exam of pelvis.
72202	X-ray exam si joints 3/> vws.
72220	X-ray exam sacrum tailbone.
73000	X-ray exam of collar bone.
73010	X-ray exam of shoulder blade.
73020	X-ray exam of shoulder.
73030	X-ray exam of shoulder.
73050	X-ray exam of shoulders.
73060	X-ray exam of humerus.
73070	X-ray exam of elbow.
73080	X-ray exam of elbow.
73090	X-ray exam of forearm.
73100	X-ray exam of wrist.
73110	X-ray exam of wrist.
73120	X-ray exam of hand.
73130	X-ray exam of hand.
73140	X-ray exam of finger(s).
73510	X-ray exam of hip.
73520	X-ray exam of hips.
73540	X-ray exam of pelvis & hips.
73550	X-ray exam of thigh.
73560	X-ray exam of knee 1 or 2.
73562	X-ray exam of knee 3.
73564	X-ray exam knee 4 or more.
73565	X-ray exam of knees.
73590	X-ray exam of lower leg.
73600	X-ray exam of ankle.
73610	X-ray exam of ankle.
73620	X-ray exam of foot.
73630	X-ray exam of foot.
73650	X-ray exam of heel.
73660	X-ray exam of toe(s).
74000	X-ray exam of abdomen.
74010	X-ray exam of abdomen.
74020	X-ray exam of abdomen.
74022	X-ray exam series abdomen.
74210	Contrst x-ray exam of throat.
74220	Contrast x-ray esophagus.
74230	Cine/vid x-ray throat/esoph.
74246	Contrst x-ray uppr gi tract.
74247	Contrst x-ray uppr gi tract.
74249	Contrst x-ray uppr gi tract.
76100	X-ray exam of body section.
76510	Ophth us b & quant a.
76511	Ophth us quant a only.
76512	Ophth us b w/non-quant a.
76513	Echo exam of eye water bath.
76514	Echo exam of eye thickness.
76516	Echo exam of eye.
76519	Echo exam of eye.
76536	Us exam of head and neck.
76645	Us exam breast(s).
76801	Ob us < 14 wks single fetus.
76805	Ob us >/= 14 wks sngl fetus.
76811	Ob us detailed sngl fetus.
76816	Ob us follow-up per fetus.
76817	Transvaginal us obstetric.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2014 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
76830	Transvaginal us non-ob.
76881	Us xtr non-vasc complete.
76882	Us xtr non-vasc lmtd.
76970	Ultrasound exam follow-up.
77072	X-rays for bone age.
77073	X-rays bone length studies.
77074	X-rays bone survey limited.
77075	X-rays bone survey complete.
77076	X-rays bone survey infant.
77077	Joint survey single view.
77082	Dxa bone density vert fx.
77084	Magnetic image bone marrow.
77300	Radiation therapy dose plan.
77301	Radiotherapy dose plan imrt.
77305	Teletx isodose plan simple.
77310	Teletx isodose plan intermed.
77315	Teletx isodose plan complex.
77327	Brachytx isodose calc interm.
77331	Special radiation dosimetry.
77336	Radiation physics consult.
77338	Design mlc device for imrt.
77370	Radiation physics consult.
80500	Lab pathology consultation.
80502	Lab pathology consultation.
85097	Bone marrow interpretation.
86510	Histoplasmosis skin test.
86850	RBC antibody screen.
86870	RBC antibody identification.
86880	Coombs test direct.
86885	Coombs test indirect qual.
86886	Coombs test indirect titer.
86890	Autologous blood process.
86900	Blood typing abo.
86901	Blood typing rh (d).
86904	Blood typing patient serum.
86905	Blood typing rbc antigens.
86906	Blood typing rh phenotype.
86930	Frozen blood prep.
86970	Rbc pretx incubatj w/chemicl.
86977	Rbc serum pretx incubj/inhib.
88104	Cytopath fl nongyn smears.
88106	Cytopath fl nongyn filter.
88108	Cytopath concentrate tech.
88112	Cytopath cell enhance tech.
88120	Cytp urne 3–5 probes ea spec.
88160	Cytopath smear other source.
88161	Cytopath smear other source.
88162	Cytopath smear other source.
88172	Cytp dx eval fna 1st ea site.
88173	Cytopath eval fna report.
88182	Cell marker study.
88184	Flowcytometry/tc 1 marker.
88185	Flowcytometry/tc add-on.
88189	Flowcytometry/read 16 & >.
88300	Surgical path gross.
88302	Tissue exam by pathologist.
88304	Tissue exam by pathologist.
88305	Tissue exam by pathologist.
88307	Tissue exam by pathologist.
88311	Decalcify tissue.
88312	Special stains group 1.
88313	Special stains group 2.
88314	Histochemical stains add-on.
88321	Microslide consultation.
88323	Microslide consultation.
88325	Comprehensive review of data.
88329	Path consult introp.
88331	Path consult intraop 1 bloc.
88342	Immunohistochemistry.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2014 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
88346	Immunofluorescent study.
88347	Immunofluorescent study.
88348	Electron microscopy.
88358	Analysis tumor.
88360	Tumor immunohistochem/manual.
88361	Tumor immunohistochem/comput.
88365	Insitu hybridization (fish).
88368	Insitu hybridization manual.
88385	Eval molecul probes 51–250.
88386	Eval molecul probes 251–500.
89049	Chct for mal hyperthermia.
89220	Sputum specimen collection.
89230	Collect sweat for test.
89240	Pathology lab procedure.
90472	Immunization admin each add.
90474	Immune admin oral/nasal addl.
92020	Special eye evaluation.
92025	Corneal topography.
92060	Special eye evaluation.
92081	Visual field examination(s).
92082	Visual field examination(s).
92083	Visual field examination(s).
92133	Cmptr ophth img optic nerve.
92134	Cptr ophth dx img post segmt.
92136	Ophthalmic biometry.
92225	Special eye exam initial.
92226	Special eye exam subsequent.
92230	Eye exam with photos.
92240	Icg angiography.
92250	Eye exam with photos.
92275	Electroretinography.
92285	Eye photography.
92286	Internal eye photography.
92520	Laryngeal function studies.
92541	Spontaneous nystagmus test.
92542	Positional nystagmus test.
92546	Sinusoidal rotational test.
92548	Posturography.
92550	Tympanometry & reflex thresh.
92552	Pure tone audiometry air.
92553	Audiometry air & bone.
92555	Speech threshold audiometry.
92556	Speech audiometry complete.
92557	Comprehensive hearing test.
92567	Tympanometry.
92570	Acoustic immitance testing.
92582	Conditioning play audiometry.
92585	Auditor evoke potent compre.
92603	Cochlear implt f/up exam 7/>.
92604	Reprogram cochlear implt 7/>.
92626	Eval aud rehab status.
93005	Electrocardiogram tracing.
93017	Cardiovascular stress test.
93225	Ecg monit/reprt up to 48 hrs.
93226	Ecg monit/reprt up to 48 hrs.
93229	Remote 30 day ecg tech supp.
93270	Remote 30 day ecg rev/report.
93271	Ecg/monitoring and analysis.
93278	ECG/signal-averaged.
93290	Icm device eval.
93306	Tte w/doppler complete.
93701	Bioimpedance cv analysis.
93786	Ambulatory BP recording.
93788	Ambulatory BP analysis.
93880	Extracranial bilat study.
93882	Extracranial uni/ltd study.
93886	Intracranial complete study.
93888	Intracranial limited study.
93922	Upr/l xtremity art 2 levels.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2014 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
93923	Upr/lxtr art stdy 3+ lvls.
93924	Lwr xtr vasc stdy bilat.
93925	Lower extremity study.
93926	Lower extremity study.
93930	Upper extremity study.
93931	Upper extremity study.
93965	Extremity study.
93970	Extremity study.
93971	Extremity study.
93975	Vascular study.
93976	Vascular study.
93978	Vascular study.
93979	Vascular study.
93990	Doppler flow testing.
94015	Patient recorded spirometry.
94690	Exhaled air analysis.
95250	Glucose monitoring cont.
95800	Slp stdy unattended.
95803	Actigraphy testing.
95805	Multiple sleep latency test.
95806	Sleep study unatt&resp efft.
95807	Sleep study attended.
95808	Polysom any age 1–3> param.
95810	Polysom 6/> yrs 4/> param.
95812	Eeg 41–60 minutes.
95813	Eeg over 1 hour.
95816	Eeg awake and drowsy.
95819	Eeg awake and asleep.
95822	Eeg coma or sleep only.
95869	Muscle test thor paraspinal.
95872	Muscle test one fiber.
95900	Motor nerve conduction test.
95921	Autonomic nrv parasym inervj.
95925	Somatosensory testing.
95926	Somatosensory testing.
95930	Visual evoked potential test.
95950	Ambulatory eeg monitoring.
95953	EEG monitoring/computer.
96000	Motion analysis video/3d.
96361	Hydrate iv infusion add-on.
96366	Ther/proph/diag iv inf addon.
96367	Tx/proph/dg addl seq iv inf.
96370	Sc ther infusion addl hr.
96371	Sc ther infusion reset pump.
96375	Tx/pro/dx inj new drug addon.
96411	Chemo iv push addl drug.
96415	Chemo iv infusion addl hr.
96417	Chemo iv infus each addl seq.
96423	Chemo ia infuse each addl hr.
G0365	Vessel mapping hemo access.
G0399	Home sleep test/type 3 Porta.
G0416	Sat biopsy 10–20.

c. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2014, we are proposing to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2014 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for

which we had CY 2012 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2011. For the CY 2014 OPPS proposed rates, we used the set of claims processed during CY 2012. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2012 (the year of claims data we used to calculate the proposed CY 2014 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2012 Data Specifications Manual.

In accordance with our longstanding policy, we calculated CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculated CCRs was the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). One longstanding exception to this general methodology for calculation of CCRs used for converting charges to costs on each claim, as detailed in the CY 2007 OPPS/ASC final rule with comment period, is the calculation of blood costs, as discussed in section II.A.2.d.(2) of this proposed rule and which has been our standard policy since the CY 2005 OPPS.

For the CCR calculation process, we used the same general approach that we used in developing the final APC rates for CY 2007 and thereafter, using the revised CCR calculation that excluded the costs of paramedical education programs and weighted the outpatient charges by the volume of outpatient services furnished by the hospital. We refer readers to the CY 2007 OPPS/ASC final rule with comment period for more information (71 FR 67983 through 67985). We first limited the population of cost reports to only those hospitals that filed outpatient claims in CY 2012 before determining whether the CCRs for such hospitals were valid.

We then calculated the CCRs for each cost center and the overall ancillary CCR for each hospital for which we had claims data. We did this using hospital-specific data from the Hospital Cost Report Information System (HCRIS). We used the most recent available cost report data, in most cases, cost reports with cost reporting periods beginning in CY 2011. For this proposed rule, we used the most recently submitted cost reports to calculate the CCRs to be used to calculate costs for the proposed CY 2014 OPPS payment rates. If the most recently available cost report was submitted but not settled, we looked at the last settled cost report to determine the ratio of submitted to settled cost using the overall ancillary CCR, and we then adjusted the most recent available submitted, but not settled, cost report using that ratio. We then calculated both an overall ancillary CCR and cost center-specific CCRs for each hospital. We used the overall ancillary CCR referenced above for all purposes that require use of an overall ancillary CCR. We are proposing to continue this longstanding methodology for the calculation of costs for CY 2014.

Since the implementation of the OPPS, some commenters have raised concerns about potential bias in the OPPS cost-based weights due to ''charge compression,'' which is the practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services. As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center. This issue was evaluated in a report by Research Triangle Institute, International (RTI). The RTI final report can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM-500-2005–0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf*. For a complete discussion of the RTI recommendations, public comments, and our responses, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527).

We addressed the RTI finding that there was aggregation bias in both the IPPS and the OPPS cost estimation of expensive and inexpensive medical supplies in the FY 2009 IPPS final rule (73 FR 48458 through 45467). Specifically, we created one cost center for ''Medical Supplies Charged to Patients'' and one cost center for ''Implantable Devices Charged to Patients,'' essentially splitting the then current cost center for ''Medical Supplies Charged to Patients'' into one cost center for low-cost medical supplies and another cost center for high-cost implantable devices in order to mitigate some of the effects of charge compression. In determining the items that should be reported in these respective cost centers, we adopted commenters' recommendations that hospitals should use revenue codes established by the AHA's NUBC to determine the items that should be reported in the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers. For a complete discussion of the rationale for the creation of the new cost center for ''Implantable Devices Charged to Patients,'' public comments, and our responses, we refer readers to the FY 2009 IPPS final rule.

The cost center for ''Implantable Devices Charged to Patients'' has been available for use for cost reporting periods beginning on or after May 1, 2009. In the CY 2013 OPPS/ASC final rule with comment period, we determined that a significant volume of hospitals were utilizing the ''Implantable Devices Charged to Patients'' cost center. Because a sufficient amount of data from which to generate a meaningful analysis was available, we established in the CY 2013 OPPS/ASC final rule with comment period a policy to create a distinct CCR using the ''Implantable Devices Charged to Patients'' cost center (77 FR 68225). For the CY 2014 OPPS, we are proposing to continue to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for use in calculating the OPPS relative payment weights.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create new standard cost centers for ''Computed Tomography (CT),'' ''Magnetic Resonance Imaging (MRI),'' and ''Cardiac Catheterization,'' and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS 2552–10. As we discussed in the FY 2009 IPPS and CY 2009 OPPS/ASC proposed and final rules, RTI also found that the costs and charges of CT scans, MRIs, and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI concluded that both the IPPS and the OPPS relative payment weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRIs, and cardiac catheterization in order for

hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the cost from charges on claims data. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a more detailed discussion on the reasons for the creation of standard cost centers for CT scans, MRIs, and cardiac catheterization. The new standard cost centers for CT scans, MRIs, and cardiac catheterization were effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

Using the December 2012 HCRIS update which we use to estimate costs in the CY 2014 OPPS ratesetting process, we were able to calculate a valid implantable device CCR for 2,936 hospitals, a valid MRI CCR for 1,853 hospitals, a valid CT scan CCR for 1,956 hospitals, and a valid Cardiac Catheterization CCR for 1,367 hospitals. We believe that there is a sufficient amount of data in the Form CMS 2552–10 cost reports from which to generate a meaningful analysis of CCRs. Therefore, we are providing various data analyses below in Tables 2 and 3 demonstrating the changes as a result of including the new CCRs calculated from the new standard cost centers into the CY 2014 OPPS ratesetting process.

TABLE 2—MEDIAN CCRS CALCULATED USING DIFFERENT COST REPORT DISTRIBUTIONS

Calculated CCR	"New" standard cost center	Using Form 2552–96 CCRs only	Using Form 2552–96 and Form 2552–10 CCRs
Cardiology	.....	0.2915	0.5112
Cardiac Catheterization	*	0.1685	0.1590
Radiology—Diagnostic	.....	0.2025	0.2279
Magnetic Resonance Imaging (MRI)	*	0.1074	0.0959
CT Scan	*	0.0568	0.0502
Medical Supplies Charged to Patient	.....	0.3389	0.3315
Implantable Devices Charged to Patient	*	0.4371	0.4190

TABLE 3—PERCENTAGE CHANGE IN ESTIMATED COST FOR THOSE APCS SIGNIFICANTLY AFFECTED BY USE OF THE NEW STANDARD COST CENTER CCRS IN THE CMS FORM 2552–10 COST REPORTS

APC	APC Descriptor	Percentage change in estimated cost (percent)
0282	Miscellaneous Computed Axial Tomography	−38.1
0332	Computed Tomography without Contrast	−34.0
8005	CT and CTA without Contrast Composite	−33.9
0331	Combined Abdomen and Pelvis CT without Contrast	−32.9
8006	CT and CTA with Contrast Composite	−29.0
0334	Combined Abdomen and Pelvis CT with Contrast	−28.8
0662	CT Angiography	−27.0
0283	Computed Tomography with Contrast	−27.0
0333	Computed Tomography without Contrast followed by Contrast	−26.3
0383	Cardiac Computed Tomographic Imaging	−24.8
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	−19.3
8008	MRI and MRA with Contrast Composite	−18.9
8007	MRI and MRA without Contrast Composite	−18.5
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast	−18.2
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	−14.9
0080	Diagnostic Cardiac Catheterization	−8.7
0276	Level I Digestive Radiology	15.2
0378	Level II Pulmonary Imaging	15.2
0396	Bone Imaging	15.5
0390	Level I Endocrine Imaging	15.8
0395	GI Tract Imaging	16.2
0402	Level II Nervous System Imaging	16.2
0398	Level I Cardiac Imaging	16.3
0262	Plain Film of Teeth	16.9
0377	Level II Cardiac Imaging	17.0
0267	Level III Diagnostic and Screening Ultrasound	17.2
0406	Level I Tumor/Infection Imaging	17.4
0403	Level I Nervous System Imaging	18.9
0266	Level II Diagnostic and Screening Ultrasound	25.1
0265	Level I Diagnostic and Screening Ultrasound	29.9
8004	Ultrasound Composite	30.2

We note that the estimated changes in geometric mean estimated APC cost of using data from the new standard cost centers cited above appear consistent with the expected results based on RTI's analysis of cost report and claims data in the July 2008 final report (pages 5 and 6), which state ''in hospitals that aggregate data for CT scanning, MRI, or

nuclear medicine services with the standard line for Diagnostic Radiology, costs for these services all appear substantially overstated, while the costs for plain films, ultrasound and other imaging procedures are correspondingly understated.'' We also note that there are limited additional impacts in the implantable device related APCs due to using the new cost report form CMS 2552–10 because the standard cost center for implantable medical devices was previously incorporated into cost report form CMS 2552–96.

As we have discussed in prior rulemaking (77 FR 68223 through 68225), once we determined that cost report data were available for analysis, we would propose, if appropriate to use the distinct CCRs described above in the calculation of the OPPS relative payment weights. We believe that the analytic findings described above support the original decision to develop distinct standard cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization, and we see no reason to further delay proposing to implement the CCRs of each of these cost centers. Therefore, beginning in CY 2014, we are proposing to calculate the OPPS relative payment weights using distinct CCRs for cardiac catheterization, CT scan, and MRI and to continue using a distinct CCR for implantable medical devices. Section XXIII. of this proposed rule includes the impacts of calculating the proposed CY 2014 OPPS relative payment weights using these new standard cost centers.

2. Proposed Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the proposed OPPS payment rates for CY 2014. The Hospital OPPS page on the CMS Web site on which this proposed rule is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available for purchase under a CMS data use agreement. The CMS Web site, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2012 claims that were used to calculate the proposed payment rates for the CY 2014 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2014, we are proposing to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2014 OPPS payments rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.f. of this proposed rule to calculate the costs we used to establish the proposed relative weights used in calculating the proposed OPPS payment rates for CY 2014 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

a. Claims Preparation

For this proposed rule, we used the CY 2012 hospital outpatient claims processed through December 31, 2012, to calculate the geometric mean costs of APCs that underpin the proposed relative payment weights for CY 2014. To begin the calculation of the proposed relative payment weights for CY 2014, we pulled all claims for outpatient services furnished in CY 2012 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (including, for example, critical access hospital (CAH) claims and hospital claims for clinical laboratory tests for persons who are neither inpatients nor outpatients of the hospital).

We then excluded claims with condition codes 04, 20, 21, and 77 because these are claims that providers submitted to Medicare knowing that no payment would be made. For example, providers submit claims with a condition code 21 to elicit an official denial notice from Medicare and document that a service is not covered. We then excluded claims for services furnished in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands because hospitals in those geographic areas are not paid under the OPPS, and, therefore, we do not use claims for services furnished in these areas in ratesetting.

We divided the remaining claims into the three groups shown below. Groups 2 and 3 comprise the 116 million claims that contain hospital bill types paid under the OPPS.

1. Claims that were not bill types 12X (Hospital Inpatient (Medicare Part B only)), 13X (Hospital Outpatient), 14X (Hospital—Laboratory Services Provided to Nonpatients), or 76X (Clinic—Community Mental Health Center). Other bill types are not paid under the OPPS; therefore, these claims were not used to set OPPS payment.

2. Claims that were bill types 12X, 13X or 14X. Claims with bill types 12X and 13X are hospital outpatient claims. Claims with bill type 14X are laboratory specimen claims, of which we use a subset for the limited number of services in these claims that are paid under the OPPS.

3. Claims that were bill type 76X (CMHC).

To convert charges on the claims to estimated cost, we multiplied the charges on each claim by the appropriate hospital-specific CCR associated with the revenue code for the charge as discussed in section II.A.1.c. of this proposed rule. We then flagged and excluded CAH claims (which are not paid under the OPPS) and claims from hospitals with invalid CCRs. The latter included claims from hospitals without a CCR; those from hospitals paid an all-inclusive rate; those from hospitals with obviously erroneous CCRs (greater than 90 or less than 0.0001); and those from hospitals with overall ancillary CCRs that were identified as outliers (that exceeded +/− 3 standard deviations from the geometric mean after removing error CCRs). In addition, we trimmed the CCRs at the cost center (that is, departmental) level by removing the CCRs for each cost center as outliers if they exceeded +/− 3 standard deviations from the geometric mean. We used a four-tiered hierarchy of cost center CCRs, which is the revenue code-to-cost center crosswalk, to match a cost center to every possible revenue code appearing in the outpatient claims that

is relevant to OPPS services, with the top tier being the most common cost center and the last tier being the default CCR. If a hospital's cost center CCR was deleted by trimming, we set the CCR for that cost center to ''missing'' so that another cost center CCR in the revenue center hierarchy could apply. If no other cost center CCR could apply to the revenue code on the claim, we used the hospital's overall ancillary CCR for the revenue code in question as the default CCR. For example, if a visit was reported under the clinic revenue code but the hospital did not have a clinic cost center, we mapped the hospital-specific overall ancillary CCR to the clinic revenue code. The revenue code-to-cost center crosswalk is available for inspection on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Revenue codes that we do not use in establishing relative costs or to model impacts are identified with an ''N'' in the revenue code-to-cost center crosswalk.

We applied the CCRs as described above to claims with bill type 12X, 13X, or 14X, excluding all claims from CAHs and hospitals in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands and claims from all hospitals for which CCRs were flagged as invalid.

We identified claims with condition code 41 as partial hospitalization services of hospitals and moved them to another file. We note that the separate file containing partial hospitalization claims is included in the files that are available for purchase as discussed above.

We then excluded claims without a HCPCS code. We moved to another file claims that contained only influenza and pneumococcal pneumonia (PPV) vaccines. Influenza and PPV vaccines are paid at reasonable cost; therefore, these claims are not used to set OPPS rates.

We next copied line-item costs for drugs, blood, and brachytherapy sources to a separate file (the lines stay on the claim, but are copied onto another file). No claims were deleted when we copied these lines onto another file. These line-items are used to calculate a per unit arithmetic and geometric mean and median cost and a per day arithmetic and geometric mean and median cost for drugs and nonimplantable biologicals, therapeutic radiopharmaceutical agents, and brachytherapy sources, as well as other information used to set payment rates, such as a unit-to-day ratio for drugs.

Prior to CY 2013, our payment policy for nonpass-through separately paid drugs and biologicals was based on a redistribution methodology that accounted for pharmacy overhead by allocating cost from packaged drugs to separately paid drugs. This methodology typically would have required us to reduce the cost associated with packaged coded and uncoded drugs in order to allocate that cost. However, for CY 2013, we paid for separately payable drugs and biologicals under the OPPS at ASP+6 percent, based upon the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. Under that policy, we did not redistribute the pharmacy overhead costs from packaged drugs to separately paid drugs. For the CY 2014 OPPS, we are proposing to continue the CY 2013 payment policy for separately payable drugs and biologicals. We refer readers to section V.B.3. of this proposed rule for a complete discussion of our CY 2014 proposed payment policy for separately paid drugs and biologicals.

We then removed line-items that were not paid during claim processing, presumably for a line-item rejection or denial. The number of edits for valid OPPS payment in the Integrated Outpatient Code Editor (I/OCE) and elsewhere has grown significantly in the past few years, especially with the implementation of the full spectrum of National Correct Coding Initiative (NCCI) edits. To ensure that we are using valid claims that represent the cost of payable services to set payment rates, we removed line-items with an OPPS status indicator that were not paid during claims processing in the claim year, but have a status indicator of ''S,'' ''T,'' or ''V,'' in the prospective year's payment system. This logic preserves charges for services that would not have been paid in the claim year but for which some estimate of cost is needed for the prospective year, such as services newly removed from the inpatient list for CY 2013 that were assigned status indicator ''C'' in the claim year. It also preserves charges for packaged services so that the costs can be included in the cost of the services with which they are reported, even if the CPT codes for the packaged services were not paid because the service is part of another service that was reported on the same claim or the code otherwise violates claims processing edits.

For CY 2014, we are proposing to continue the policy we implemented for CY 2013 to exclude line-item data for pass-through drugs and biologicals (status indicator ''G'' for CY 2012) and nonpass-through drugs and biologicals (status indicator ''K'' for CY 2012) where the charges reported on the claim for the line were either denied or rejected during claims processing. Removing lines that were eligible for payment but were not paid ensures that we are using appropriate data. The trim avoids using cost data on lines that we believe were defective or invalid because those rejected or denied lines did not meet the Medicare requirements for payment. For example, edits may reject a line for a separately paid drug because the number of units billed exceeded the number of units that would be reasonable and, therefore, is likely a billing error (for example, a line reporting 55 units of a drug for which 5 units is known to be a fatal dose). As with our trimming in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68226) of line-items with a status indicator of ''S,'' ''T,'' ''V,'' or ''X,'' we believe that unpaid line-items represent services that are invalidly reported and, therefore, should not be used for ratesetting. We believe that removing lines with valid status indicators that were edited and not paid during claims processing increases the accuracy of the data used for ratesetting purposes.

For the CY 2014 OPPS, as part of the proposal to package clinical diagnostic laboratory tests, we also are proposing to apply the line item trim to these services if they did not receive payment in the claims year. Removing these lines ensures that, in establishing the CY 2014 OPPS relative payments weights, we appropriately allocate the costs associated with packaging these services. For a more detailed discussion of the proposal to package clinical diagnostic laboratory tests, we refer readers to section II.A.3.b.(3) of this proposed rule.

b. Splitting Claims and Creation of ''Pseudo'' Single Procedure Claims

(1) Splitting Claims

For the CY 2014 OPPS, we then split the remaining claims into five groups: single majors; multiple majors; single minors; multiple minors; and other claims. (Specific definitions of these groups are presented below.) We note that, under the proposed CY 2014 OPPS packaging policy, we are proposing to delete status indicator ''X'' and revise the title and description of status indicator ''Q1'' to reflect that deletion, as discussed in sections II.A.3. and XI. of this proposed rule. For CY 2014, we are proposing to define major procedures as any HCPCS code having a status indicator of ''S,'' ''T,'' or ''V''; to define minor procedures as any code

having a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N''; and to classify ''other'' procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2014, we are proposing to continue to assign status indicator ''R'' to blood and blood products; status indicator ''U'' to brachytherapy sources; status indicator ''Q1'' to all ''STV-packaged codes''; status indicator ''Q2'' to all ''T-packaged codes''; and status indicator ''Q3'' to all codes that may be paid through a composite APC based on composite-specific criteria or paid separately through single code APCs when the criteria are not met.

As discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68709), we established status indicators ''Q1,'' ''Q2,'' and ''Q3'' to facilitate identification of the different categories of codes. We are proposing to treat these codes in the same manner for data purposes for CY 2014 as we have treated them since CY 2008. Specifically, we are continuing to evaluate whether the criteria for separate payment of codes with status indicator ''Q1'' or ''Q2'' are met in determining whether they are treated as major or minor codes. Codes with status indicator ''Q1'' or ''Q2'' are carried through the data either with status indicator ''N'' as packaged or, if they meet the criteria for separate payment, they are given the status indicator of the APC to which they are assigned and are considered as ''pseudo'' single procedure claims for major codes. Codes assigned status indicator ''Q3'' are paid under individual APCs unless they occur in the combinations that qualify for payment as composite APCs and, therefore, they carry the status indicator of the individual APC to which they are assigned through the data process and are treated as major codes during both the split and ''pseudo'' single creation process. The calculation of the geometric mean costs for composite APCs from multiple procedure major claims is discussed in section II.A.2.f. of this proposed rule.

Specifically, we are proposing to divide the remaining claims into the following five groups:

1. *Single Procedure Major Claims:* Claims with a single separately payable procedure (that is, status indicator ''S,'' ''T,'' or ''V'' which includes codes with status indicator ''Q3''); claims with one unit of a status indicator ''Q1'' code (''STV-packaged'') where there was no code with status indicator ''S,'' ''T,'' or ''V'' on the same claim on the same date; or claims with one unit of a status indicator ''Q2'' code (''T-packaged'') where there was no code with a status indicator ''T'' on the same claim on the same date.

2. *Multiple Procedure Major Claims:* Claims with more than one separately payable procedure (that is, status indicator ''S,'' ''T,'' or ''V,'' which includes codes with status indicator ''Q3''), or multiple units of one payable procedure. These claims include those codes with a status indicator ''Q2'' code (''T-packaged'') where there was no procedure with a status indicator ''T'' on the same claim on the same date of service but where there was another separately paid procedure on the same claim with the same date of service (that is, another code with status indicator ''S '' or ''V''). We also include in this set claims that contained one unit of one code when the bilateral modifier was appended to the code and the code was conditionally or independently bilateral. In these cases, the claims represented more than one unit of the service described by the code, notwithstanding that only one unit was billed.

3. *Single Procedure Minor Claims:* Claims with a single HCPCS code that was assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N'' and not status indicator ''Q1'' (''STV-packaged'') or status indicator ''Q2'' (''T-packaged'') code.

4. *Multiple Procedure Minor Claims:* Claims with multiple HCPCS codes that are assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N''; claims that contain more than one code with status indicator ''Q1'' (''STV-packaged'') or more than one unit of a code with status indicator ''Q1'' but no codes with status indicator ''S,'' ''T,'' or ''V'' on the same date of service; or claims that contain more than one code with status indicator ''Q2'' (T-packaged), or ''Q2'' and ''Q1,'' or more than one unit of a code with status indicator ''Q2'' but no code with status indicator ''T'' on the same date of service.

5. *Non-OPPS Claims:* Claims that contain no services payable under the OPPS (that is, all status indicators other than those listed for major or minor status). These claims were excluded from the files used for the OPPS. Non-OPPS claims have codes paid under other fee schedules, for example, durable medical equipment, and do not contain a code for a separately payable or packaged OPPS service. Non-OPPS claims include claims for therapy services paid sometimes under the OPPS but billed, in these non-OPPS cases, with revenue codes indicating that the therapy services would be paid under the Medicare Physician Fee Schedule (MPFS).

The claims listed in numbers 1, 2, 3, and 4 above are included in the data file that can be purchased as described above. Claims that contain codes to which we have assigned status indicators ''Q1'' (''STV-packaged'') and ''Q2'' (''T-packaged'') appear in the data for the single major file, the multiple major file, and the multiple minor file used for ratesetting. Claims that contain codes to which we have assigned status indicator ''Q3'' (composite APC members) appear in both the data of the single and multiple major files used in this proposed rule, depending on the specific composite calculation.

(2) Creation of ''Pseudo'' Single Procedure Claims

To develop ''pseudo'' single procedure claims for this proposed rule, we examined both the multiple procedure major claims and the multiple procedure minor claims. We first examined the multiple major procedure claims for dates of service to determine if we could break them into ''pseudo'' single procedure claims using the dates of service for all lines on the claim. If we could create claims with single major procedures by using dates of service, we created a single procedure claim record for each separately payable procedure on a different date of service (that is, a ''pseudo'' single procedure claim).

We also are proposing to use the bypass codes listed in Addendum N to this proposed rule (which is available via the Internet on our Web site) and discussed in section II.A.1.b. of this proposed rule to remove separately payable procedures which we determined contained limited or no packaged costs or that were otherwise suitable for inclusion on the bypass list from a multiple procedure bill. As discussed above, we ignore the ''overlap bypass codes,'' that is, those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs, in this initial assessment for ''pseudo'' single procedure claims. The proposed CY 2014 ''overlap bypass codes'' are listed in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site). When one of the two separately payable procedures on a multiple procedure claim was on the bypass list, we split the claim into two ''pseudo'' single procedure claim records. The single procedure claim record that contained the bypass code did not retain packaged services. The single procedure claim record that contained the other separately payable procedure (but no bypass code) retained the packaged revenue code charges and

the packaged HCPCS code charges. We also removed lines that contained multiple units of codes on the bypass list and treated them as ''pseudo'' single procedure claims by dividing the cost for the multiple units by the number of units on the line. If one unit of a single, separately payable procedure code remained on the claim after removal of the multiple units of the bypass code, we created a ''pseudo'' single procedure claim from that residual claim record, which retained the costs of packaged revenue codes and packaged HCPCS codes. This enabled us to use claims that would otherwise be multiple procedure claims and could not be used.

We then assessed the claims to determine if the proposed criteria for the multiple imaging composite APCs, discussed in section II.A.2.f.(5) of this proposed rule, were met. If the criteria for the imaging composite APCs were met, we created a ''single session'' claim for the applicable imaging composite service and determined whether we could use the claim in ratesetting. For HCPCS codes that are both conditionally packaged and are members of a multiple imaging composite APC, we first assessed whether the code would be packaged and, if so, the code ceased to be available for further assessment as part of the composite APC. Because the packaged code would not be a separately payable procedure, we considered it to be unavailable for use in setting the composite APC costs on which the proposed CY 2014 OPPS payments are based. Having identified ''single session'' claims for the imaging composite APCs, we reassessed the claim to determine if, after removal of all lines for bypass codes, including the ''overlap bypass codes,'' a single unit of a single separately payable code remained on the claim. If so, we attributed the packaged costs on the claim to the single unit of the single remaining separately payable code other than the bypass code to create a ''pseudo'' single procedure claim. We also identified line-items of overlap bypass codes as a ''pseudo'' single procedure claim. This allowed us to use more claims data for ratesetting purposes.

We also are proposing to examine the multiple procedure minor claims to determine whether we could create ''pseudo'' single procedure claims. Specifically, where the claim contained multiple codes with status indicator ''Q1'' (''STV-packaged'') on the same date of service or contained multiple units of a single code with status indicator ''Q1,'' we selected the status indicator ''Q1'' HCPCS code that had the highest CY 2013 relative payment weight, set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q1.'' We then packaged all costs for the following into a single cost for the ''Q1'' HCPCS code that had the highest CY 2013 relative payment weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q1'' HCPCS code with the highest CY 2013 relative payment weight; other codes with status indicator ''Q1''; and all other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from the data status indicator of ''N'' to the status indicator of the APC to which the selected procedure was assigned for further data processing and considered this claim as a major procedure claim. We used this claim in the calculation of the APC geometric mean cost for the status indicator ''Q1'' HCPCS code.

Similarly, if a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') or multiple units of a single code with status indicator ''Q2,'' we selected the status indicator ''Q2'' HCPCS code that had the highest CY 2013 relative payment weight and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the ''Q2'' HCPCS code that had the highest CY 2013 relative payment weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2013 relative payment weight; other codes with status indicator ''Q2''; and other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned, and we considered this claim as a major procedure claim.

If a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') and status indicator ''Q1'' (''STV-packaged''), we selected the T-packaged status indicator ''Q2'' HCPCS code that had the highest relative payment weight for CY 2013 and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the selected (''T packaged'') HCPCS code to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2013 relative payment weight; other codes with status indicator ''Q2''; codes with status indicator ''Q1'' (''STV-packaged''); and other packaged HCPCS codes and packaged revenue code costs. We selected status indicator ''Q2'' HCPCS codes instead of ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2013 relative payment weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2013 relative payment weight, it became the primary code for the simulated single bill process. We changed the status indicator for the selected status indicator ''Q2'' (''T-packaged'') code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned and we considered this claim as a major procedure claim.

We then applied our proposed process for creating ''pseudo'' single procedure claims to the conditionally packaged codes that do not meet the criteria for packaging, which enabled us to create single procedure claims from them, if they met the criteria for single procedure claims. Conditionally packaged codes are identified using status indicators ''Q1'' and ''Q2,'' and are described in section XI.A. of this proposed rule.

Lastly, we excluded those claims that we were not able to convert to single procedure claims even after applying all of the techniques for creation of ''pseudo'' single procedure claims to multiple procedure major claims and to multiple procedure minor claims. As has been our practice in recent years, we also excluded claims that contained codes that were viewed as independently or conditionally bilateral and that contained the bilateral modifier (Modifier 50 (Bilateral procedure)) because the line-item cost for the code represented the cost of two units of the procedure, notwithstanding that hospitals billed the code with a unit of one.

We are proposing to continue to apply the methodology described above for the purpose of creating ''pseudo'' single procedure claims for the CY 2014 OPPS.

c. Completion of Claim Records and Geometric Mean Cost Calculations

(1) General Process

We then packaged the costs of packaged HCPCS codes (codes with status indicator ''N'' listed in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and the costs of those

lines for codes with status indicator ''Q1'' or ''Q2'' when they are not separately paid), and the costs of the services reported under packaged revenue codes in Table 4 below that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim. For a more complete discussion of our proposed CY 2014 OPPS packaging policy, we refer readers to section II.A.3. of this proposed rule.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66606), for the CY 2008 OPPS, we adopted an APC Panel recommendation that CMS should review the final list of packaged revenue codes for consistency with OPPS policy and ensure that future versions of the I/OCE edit accordingly. As we have in the past, we are proposing to continue to compare the final list of packaged revenue codes that we adopt for CY 2014 to the revenue codes that the I/OCE will package for CY 2014 to ensure consistency.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68531), we replaced the NUBC standard abbreviations for the revenue codes listed in Table 2 of the CY 2009 OPPS/ASC proposed rule with the most current NUBC descriptions of the revenue code categories and subcategories to better articulate the meanings of the revenue codes without changing the list of revenue codes. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60362 through 60363), we finalized changes to the packaged revenue code list based on our examination of the updated NUBC codes and public comment on the CY 2010 proposed list of packaged revenue codes.

For CY 2014, as we did for CY 2013, we reviewed the changes to revenue codes that were effective during CY 2012 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we would propose to package for CY 2014. We believe that the charges reported under the revenue codes listed in Table 4 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2014, we are proposing to continue to package the costs that we derive from the charges reported without HCPCS codes under the revenue codes displayed in Table 4 below for purposes of calculating the geometric mean costs on which the proposed CY 2014 OPPS/ASC payment rates are based.

TABLE 4—PROPOSED CY 2014 PACKAGED REVENUE CODES

Revenue code	Description
0250	Pharmacy; General Classification.
0251	Pharmacy; Generic Drugs.
0252	Pharmacy; Non-Generic Drugs.
0254	Pharmacy; Drugs Incident to Other Diagnostic Services.
0255	Pharmacy; Drugs Incident to Radiology.
0257	Pharmacy; Non-Prescription.
0258	Pharmacy; IV Solutions.
0259	Pharmacy; Other Pharmacy.
0260	IV Therapy; General Classification.
0261	IV Therapy; Infusion Pump.
0262	IV Therapy; IV Therapy/Pharmacy Svcs.
0263	IV Therapy; IV Therapy/Drug/Supply Delivery.
0264	IV Therapy; IV Therapy/Supplies.
0269	IV Therapy; Other IV Therapy.
0270	Medical/Surgical Supplies and Devices; General Classification.
0271	Medical/Surgical Supplies and Devices; Non-sterile Supply.
0272	Medical/Surgical Supplies and Devices; Sterile Supply.
0275	Medical/Surgical Supplies and Devices; Pacemaker.
0276	Medical/Surgical Supplies and Devices; Intraocular Lens.
0278	Medical/Surgical Supplies and Devices; Other Implants.
0279	Medical/Surgical Supplies and Devices; Other Supplies/Devices.
0280	Oncology; General Classification.
0289	Oncology; Other Oncology.
0343	Nuclear Medicine; Diagnostic Radiopharmaceuticals.
0344	Nuclear Medicine; Therapeutic Radiopharmaceuticals.
0370	Anesthesia; General Classification.
0371	Anesthesia; Anesthesia Incident to Radiology.
0372	Anesthesia; Anesthesia Incident to Other DX Services.
0379	Anesthesia; Other Anesthesia.
0390	Administration, Processing and Storage for Blood and Blood Components; General Classification.
0392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage.
0399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling.
0621	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Radiology.
0622	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Other DX Services.
0623	Medical Supplies—Extension of 027X, Surgical Dressings.
0624	Medical Surgical Supplies—Extension of 027X; FDA Investigational Devices.
0630	Pharmacy—Extension of 025X; Reserved.
0631	Pharmacy—Extension of 025X; Single Source Drug.
0632	Pharmacy—Extension of 025X; Multiple Source Drug.
0633	Pharmacy—Extension of 025X; Restrictive Prescription.
0681	Trauma Response; Level I Trauma.
0682	Trauma Response; Level II Trauma.
0683	Trauma Response; Level III Trauma.
0684	Trauma Response; Level IV Trauma.
0689	Trauma Response; Other.

TABLE 4—PROPOSED CY 2014 PACKAGED REVENUE CODES—Continued

Revenue code	Description
0700	Cast Room; General Classification.
0710	Recovery Room; General Classification.
0720	Labor Room/Delivery; General Classification.
0721	Labor Room/Delivery; Labor.
0732	EKG/ECG (Electrocardiogram); Telemetry.
0762	Specialty services; Observation Hours.
0801	Inpatient Renal Dialysis; Inpatient Hemodialysis.
0802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD).
0803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD).
0804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD).
0809	Inpatient Renal Dialysis; Other Inpatient Dialysis.
0810	Acquisition of Body Components; General Classification.
0819	Acquisition of Body Components; Other Donor.
0821	Hemodialysis-Outpatient or Home; Hemodialysis Composite or Other Rate.
0824	Hemodialysis-Outpatient or Home; Maintenance—100%.
0825	Hemodialysis-Outpatient or Home; Support Services.
0829	Hemodialysis-Outpatient or Home; Other OP Hemodialysis.
0942	Other Therapeutic Services (also see 095X, an extension of 094x); Education/Training.
0943	Other Therapeutic Services (also see 095X, an extension of 094X), Cardiac Rehabilitation.
0948	Other Therapeutic Services (also see 095X, an extension of 094X), Pulmonary Rehabilitation.

In accordance with our longstanding policy, we are proposing to continue to exclude: (1) Claims that had zero costs after summing all costs on the claim; and (2) claims containing packaging flag number 3. Effective for services furnished on or after July 1, 2004, the I/OCE assigned packaging flag number 3 to claims on which hospitals submitted token charges less than $1.01 for a service with status indicator ''S'' or ''T'' (a major separately payable service under the OPPS) for which the fiscal intermediary or Medicare administrative contractor (MAC) was required to allocate the sum of charges for services with a status indicator equaling ''S'' or ''T'' based on the relative payment weight of the APC to which each code was assigned. We do not believe that these charges, which were token charges as submitted by the hospital, are valid reflections of hospital resources. Therefore, we deleted these claims. We also deleted claims for which the charges equaled the revenue center payment (that is, the Medicare payment) on the assumption that, where the charge equaled the payment, to apply a CCR to the charge would not yield a valid estimate of relative provider cost. We are proposing to continue these processes for the CY 2014 OPPS.

For the remaining claims, we are proposing to then standardize 60 percent of the costs of the claim (which we have previously determined to be the labor-related portion) for geographic differences in labor input costs. We made this adjustment by determining the wage index that applied to the hospital that furnished the service and dividing the cost for the separately paid HCPCS code furnished by the hospital by that wage index. The claims accounting that we provide for the proposed and final rule contains the formula we use to standardize the total cost for the effects of the wage index. As has been our policy since the inception of the OPPS, we are proposing to use the pre-reclassified wage indices for standardization because we believe that they better reflect the true costs of items and services in the area in which the hospital is located than the post-reclassification wage indices and, therefore, would result in the most accurate unadjusted geometric mean costs.

In accordance with our longstanding practice, we also are proposing to exclude single and ''pseudo'' single procedure claims for which the total cost on the claim was outside 3 standard deviations from the geometric mean of units for each HCPCS code on the bypass list (because, as discussed above, we used claims that contain multiple units of the bypass codes).

After removing claims for hospitals with error CCRs, claims without HCPCS codes, claims for immunizations not covered under the OPPS, and claims for services not paid under the OPPS, approximately 112 million claims were left. Using these approximately 112 million claims, we created approximately 82 million single and ''pseudo'' single procedure claims, of which we used slightly more than 82 million single bills (after trimming out approximately 1 million claims as discussed in section II.A.1.a. of this proposed rule) in the CY 2014 geometric mean cost development and ratesetting.

As discussed above, the OPPS has historically developed the relative weights on which APC payments are based using APC median costs. For the CY 2013 OPPS, we calculated the APC relative payment weights using geometric mean costs, and are proposing to do the same for CY 2014. Therefore, the following discussion of the 2 times rule violation and the development of the relative payment weight refers to geometric means. For more detail about the CY 2014 OPPS/ASC policy to calculate relative payment weights based on geometric means, we refer readers to section II.A.2.f. of this proposed rule.

We are proposing to use these claims to calculate the CY 2014 geometric mean costs for each separately payable HCPCS code and each APC. The comparison of HCPCS code-specific and APC geometric mean costs determines the applicability of the 2 times rule. Section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group shall not be treated as comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the same group (the 2 times rule). While we have historically applied the 2 times rule based on median costs, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68270), as part of the CY 2013 policy to develop the OPPS relative payment weights based on geometric mean costs, we also applied

the 2 times rule based on geometric mean costs. For the CY 2014 OPPS, we are proposing to continue to develop the APC relative payment weights based on geometric mean costs.

We note that, for purposes of identifying significant HCPCS codes for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC geometric mean cost to be significant. This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 82 million single procedure or single session claims we use for establishing geometric mean costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC geometric mean. We note that this method of identifying significant HCPCS codes within an APC for purposes of the 2 times rule was used in prior years under the median-based cost methodology. Under our proposed CY 2014 policy to continue to base the relative payment weights on geometric mean costs, we believe that this same consideration for identifying significant HCPCS codes should apply because the principles are consistent with their use in the median-based cost methodology. Unlisted codes are not used in establishing the percent of claims contributing to the APC, nor are their costs used in the calculation of the APC geometric mean. Finally, we reviewed the geometric mean costs for the services for which we are proposing to pay separately under this proposed rule, and we reassigned HCPCS codes to different APCs where it was necessary to ensure clinical and resource homogeneity within the APCs. The APC geometric means were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific geometric means and the APC geometric means were weighted to account for the inclusion of multiple units of the bypass codes in the creation of ''pseudo'' single procedure claims.

As we discuss in sections II.A.2.d. and II.A.2.f. and in section VIII.B. of this proposed rule, in some cases, APC geometric mean costs are calculated using variations of the process outlined above. Specifically, section II.A.2.d. of this proposed rule addresses the proposed calculation of single APC criteria-based geometric mean costs. Section II.A.2.f. of this proposed rule discusses the proposed calculation of composite APC criteria-based geometric mean costs. Section VIII.B. of this proposed rule addresses the methodology for calculating the proposed geometric mean costs for partial hospitalization services.

(2) Recommendations of the Advisory Panel on Hospital Outpatient Payment Regarding Data Development

At the March 11, 2013 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel), we provided the Data Subcommittee with a list of all APCs fluctuating by greater than 10 percent when comparing the CY 2013 OPPS/ASC final rule costs based on CY 2011 claims processed through June 30, 2012, to those based on CY 2012 OPPS/ASC final rule data (CY 2011 claims processed through June 30, 2011). The Data Subcommittee reviewed the fluctuations in the APC costs and their respective weights.

At the March 2013 Panel meeting, the Panel made a number of recommendations related to the data process. The Panel's recommendations and our responses follow.

Recommendation: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response: We are accepting this recommendation.

Recommendation: The panel recommended that CMS provide data on the impact of the CY 2013 method of using geometric mean costs rather than median costs to establish relative APC weights.

CMS Response: We are accepting this recommendation and will provide the data at a future meeting.

d. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Device-Dependent APCs

Historically, device-dependent APCs are populated by HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure. The standard methodology for calculating device-dependent APC costs utilizes claims data that generally reflect the full cost of the required device by using only the subset of single procedure claims that pass the procedure-to-device and device-to-procedure edits; do not contain token charges (less than $1.01) for devices; do not contain the ''FB'' modifier signifying that the device was furnished without cost to the provider, or where a full credit was received; and do not contain the ''FC'' modifier signifying that the hospital received partial credit for the device. For a full history of how we have calculated payment rates for device-dependent APCs in previous years and a detailed discussion of how we developed the standard device-dependent APC ratesetting methodology, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66739 through 66742). Overviews of the procedure-to-device edits and device-to-procedure edits used in ratesetting for device-dependent APCs are available in the CY 2005 OPPS final rule with comment period (69 FR 65761 through 65763) and the CY 2007 OPPS/ASC final rule with comment period (71 FR 68070 through 68071).

For CY 2014, we are proposing in section II.A.2.e. of this proposed rule to define 29 device-dependent APCs as single complete services and to assign them to comprehensive APCs that would provide all-inclusive payments for those services. As we explain in that section, we are proposing this as a further step to improve the accuracy and transparency of our payments for these services where the cost of the device is large compared to the other costs that contribute to the cost of the service. Table 5 below provides a list of the 39 APCs currently recognized as device-dependent APCs and identifies those 29 APCs that we are proposing to include in the comprehensive APCs proposal. We are proposing to treat the remaining 10 device-dependent APCs by applying our standard APC ratesetting methodology to calculate their CY 2014 payment rates. We initially adopted a specific device-dependent APC ratesetting methodology because commenters had previously expressed concerns that the costs associated with certain high-cost devices were not always being accurately reported and included in the calculation of relative payment weights for the associated procedures. In this proposed rule, we do not believe that it is necessary to continue to apply the more specific device-dependent APC ratesetting methodology to ensure accurate ratesetting for the 10 APCs that are not included in the comprehensive APCs proposal because hospitals now have had several years of experience reporting procedures involving implantable devices and have grown accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those devices. Therefore, we believe that it is possible to calculate the payment rates for these APCs using our standard APC ratesetting methodology.

Beginning in CY 2014, we also are proposing to no longer implement procedure-to-device edits and device-to-procedure edits for any APCs. Under this proposal, hospitals would still be expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. However, claims would no longer be returned to providers when specific procedure and device code pairings do not appear on a claim. We believe that this is appropriate because of the experience hospitals now have had in coding and reporting these claims fully and because, for the more costly devices, the proposed comprehensive APCs would reliably reflect the cost of the device if it is included anywhere on the claim. Therefore, we do not believe that the burden on hospitals of adhering to the procedure-to-device edits and device-to-procedure edits, and the burden on the Medicare program of maintaining those edits, continue to be warranted. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

TABLE 5—APCs CURRENTLY RECOGNIZED AS DEVICE–DEPENDENT APCs

APC	APC Title
0039*	Level I Implantation of Neurostimulator Generator.
0040*	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.
0061*	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes.
0082*	Coronary or Non-Coronary Atherectomy.
0083*	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization.
0084	Level I Electrophysiologic Procedures.
0085*	Level II Electrophysiologic Procedures.
0086	Level III Electrophysiologic Procedures.
0089*	Insertion/Replacement of Permanent Pacemaker and Electrodes.
0090*	Level I Insertion/Replacement of Permanent Pacemaker.
0104*	Transcatheter Placement of Intracoronary Stents.
0106*	Insertion/Replacement of Pacemaker Leads and/or Electrodes.
0107*	Level I Implantation of Cardioverter-Defibrillators (ICDs).
0108*	Level II Implantation of Cardioverter-Defibrillators (ICDs).
0115	Cannula/Access Device Procedures.
0202*	Level VII Female Reproductive Procedures.
0227*	Implantation of Drug Infusion Device.
0229*	Level II Endovascular Revascularization of the Lower Extremity.
0259*	Level VII ENT Procedures.
0293*	Level VI Anterior Segment Eye Procedures.
0315*	Level II Implantation of Neurostimulator Generator.
0318*	Implantation of Neurostimulator Pulse Generator and Electrode.
0319*	Level III Endovascular Revascularization of the Lower Extremity.
0384	GI Procedures with Stents.
0385*	Level I Prosthetic Urological Procedures.
0386*	Level II Prosthetic Urological Procedures.
0425*	Level II Arthroplasty or Implantation with Prosthesis.
0427	Level II Tube or Catheter Changes or Repositioning.
0622	Level II Vascular Access Procedures.
0623	Level III Vascular Access Procedures.
0648*	Level IV Breast Surgery.
0652	Insertion of Intraperitoneal and Pleural Catheters.
0653	Vascular Reconstruction/Fistula Repair with Device.
0654*	Level II Insertion/Replacement of Permanent Pacemaker.
0655*	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing.
0656*	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0674*	Prostate Cryoablation.
0680*	Insertion of Patient Activated Event Recorders.
0687	Revision/Removal of Neurostimulator Electrodes.

*Denotes proposed comprehensive APC.

(2) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

For CY 2014, we are proposing to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we are proposing to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio

of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We would then apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We calculated the costs upon which the proposed CY 2014 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe the hospital-specific, blood-specific CCR methodology best responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that this methodology in CY 2014 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that, as discussed in section II.A.2.e. of this proposed rule, we are proposing comprehensive APCs that would provide all-inclusive payments for certain device-dependent procedures. Under this proposal, we would include the costs of blood and blood products when calculating the overall costs of these comprehensive APCs. We note that we would continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the comprehensive APCs. Because the costs of blood and blood products would be reflected in the overall costs of the comprehensive APCs (and, as a result, in the payment rates of the comprehensive APCs), we would not make separate payments for blood and blood products when they appear on the same claims as services assigned to the comprehensive APCs.

We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2014 payment rates for blood and blood products (which are identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

e. Proposed Establishment of Comprehensive APCs

(1) Definition and General Principles

During the initial development of a proposal for an outpatient prospective payment system in 1998 (63 FR 47552 through 48036), we considered developing the payment system based on a comprehensive outpatient bundle, as opposed to on a HCPCS component level. In 2000, we implemented an OPPS based generally on making payments at the HCPCS level (65 FR 18434 through 18820). Since then, however, we have been steadily moving the OPPS towards a more comprehensive approach that increases flexibility and opportunity for efficiencies in a prospective system.

For CY 2014, we are proposing to create 29 comprehensive APCs to replace 29 existing device-dependent APCs. We are proposing to define a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, our proposal is to make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service. Specifically, we are proposing to create comprehensive APCs for the 29 most costly device-dependent services, where the cost of the device is large compared to the other costs that contribute to the cost of delivering the primary service.

We believe that, under the authority of sections 1833(t)(1) and (t)(2) of the Act, the Secretary has the discretion to establish comprehensive APCs as part of developing the OPPS classification system, and that this proposal furthers our ongoing efforts to move the OPPS towards a more comprehensive payment system in support of our objectives to increase flexibility and efficiencies.

The OPPS data we have accumulated over the past decade have enabled us to continue to address several longstanding goals, including: Continuing to improve the validity of our payments to most accurately reflect costs; improving transparency and reducing complexity and administrative burden whenever possible; and increasing flexibility for hospitals to develop increased efficiencies in the delivery of quality care.

We believe this proposal to establish comprehensive APCs will improve our ability to accurately set payment rates. In the normal process of setting payment rates, costs in certain cost centers (''uncoded costs'') are added to the costs of services reported with specific HCPCS codes only when they can be reliably assigned to a single service. Under the proposal, the entire claim would be associated with a single comprehensive service so all costs reported on the claim may be reliably assigned to that service. This increases the accuracy of the payment for the comprehensive service and also increases the stability of the payment from year to year. As an example, room and board revenue center charges are not included in OPPS rate setting calculations because room and board is typically not separately charged for outpatient services. In the case of these 29 device-dependent procedures, the patient typically stays overnight to recover from the procedure. Thus, for these 29 comprehensive services, the cost of the room, nutrition (board) and nursing care that is required to sustain the patient while the comprehensive device-dependent service is delivered will be associated with the service even if the hospital reports the costs in room and board revenue codes that are not usually used to report outpatient procedure costs.

We also believe our proposal will enhance beneficiary understanding and transparency. Typically beneficiaries understand the primary procedure to be the OPPS service they receive, and do not generally consider that the other HCPCS codes are separate services. For example, beneficiaries think of a single service such as ''getting my gall bladder removed'' or ''getting a pacemaker.'' We believe that defining certain services within the OPPS in terms of a single comprehensive service delivered to the beneficiary improves transparency for the beneficiary, for physicians, and for hospitals by creating a common reference point with a similar meaning for all three groups and using the comprehensive service concept that already identifies these same services when they are performed in an inpatient environment.

Finally, we believe that larger bundles that contain a wider mix of related services in the prospectively paid bundles increase the opportunities for

providers to tailor services to the specific needs of individual beneficiaries, thereby increasing the opportunities for efficiencies and improving the delivery of medical care.

(2) Comprehensive APCs for Device-Dependent Services

(a) Identification of High-Cost Device-Dependent Procedures

In order to identify those services for which comprehensive packaging would have the greatest impact on cost validity, payment accuracy, beneficiary transparency, and hospital efficiency, we ranked all APCs by CY 2012 costs and then identified 29 device-dependent APCs where we believe that the device-dependent APC is characterized by a costly primary service with relatively small cost contributions from adjunctive services.

(b) Proposal To Create Comprehensive APCs for Certain Device-Dependent Procedures

For CY 2014, we are proposing to create 29 comprehensive APCs to prospectively pay for device-dependent services associated with 136 HCPCS codes. We are proposing to base the single all-inclusive comprehensive APC payment on all charges on the claim, excluding only charges that cannot be covered by Medicare Part B or that are not payable under the OPPS. This comprehensive APC payment would include, for example, payment for the following types of services.

• Inclusion of Otherwise Packaged Services and Supplies

As part of the comprehensive APC, we are proposing to package all services that are packaged in CY 2013, and all services proposed for unconditional or conditional packaging for CY 2014.

• Inclusion of Adjunctive Services

We have previously noted in section II.A.3.a. of this proposed rule that it has been a goal of the OPPS to package services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service. We are proposing to package into the comprehensive APCs all these integral, ancillary, supportive, dependent, and adjunctive services, hereinafter collectively referred to as ''adjunctive services,'' provided during the delivery of the comprehensive service. This includes the diagnostic procedures, laboratory tests and other diagnostic tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that are provided during the comprehensive service, except for mammography services and ambulance services, which are never payable as OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act.

• Inclusion of Devices, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

As part of the comprehensive service packaging proposal described above, we are proposing to package all devices; implantable durable medical equipment (DME); implantable prosthetics; DME, prosthetics, and orthotics when used as supplies in the delivery of the comprehensive service; and supplies used in support of these items when these items or supplies are provided as part of the delivery of a comprehensive service. We have a longstanding policy of providing payment under the OPPS for implantable DME, implantable prosthetics, and medical and surgical supplies, as provided at sections 1833(t)(1)(B)(i) and(iii) of the Act and 42 CFR 419.2(b)(4), (b)(10), and (b)(11). Under this proposal, DME, prosthetics, and orthotics, when used as supplies in the delivery of the comprehensive service, would be covered OPD services as provided under section 1833(t)(1)(B)(i) of the Act and 42 CFR 419.2(b)(4). Under this proposal, we believe that when such items and services are provided as adjunctive components in the delivery of a comprehensive service, such items are appropriate for coverage under the OPPS as covered OPD services, and for payment under the OPPS. We note that, at other times, such items when not provided as adjunctive components in the delivery of a comprehensive service would not constitute covered OPD services, and such items would be appropriately provided by suppliers and paid for under the DMEPOS benefit. More specifically, we do not believe that this proposed policy limits a hospital's ability to function as a DMEPOS supplier and bill DMEPOS items to the DME–MAC when those items are unrelated to the outpatient procedure and provided outside of the delivery of the comprehensive service.

In summary, we are proposing to consider all DMEPOS items to be covered OPD services and to be adjunctive to the primary service when they are delivered during the comprehensive service, as described above, and, therefore, are proposing to package such items into the applicable comprehensive service. This proposal includes any items described by codes that are otherwise covered and paid separately in accordance with the payment rules for DMEPOS items and services, and applies to those items when they are provided as part of the delivery of the comprehensive service. Under this proposal, when such items are provided during the delivery of a comprehensive service, we are proposing that they are covered OPD services as provided under sections 1833(t)(1)(B)(i) and (iii) of the Act and 42 CFR 419.2(b)(4), (b)(10), and (b)(11), and payable under the OPPS, as described above.

• Inclusion of OPD Services Reported by Therapy Codes

Generally, section 1833(t)(1)(B)(4) of the Act excludes therapy services from the OPPS. We have previously noted that therapy services are those provided by therapists under a plan of care, and are paid under section 1834(k) of the Act subject to an annual therapy cap, when applied. However, certain other activities similar to therapy services are considered and paid as outpatient services. Although some adjunctive services may be provided by therapists and reported with therapy codes, we do not believe they always constitute therapy services. In the case of adjunctive components of a comprehensive service that are described by codes that would, under other circumstances, be indicative of therapy services, we note that there are a number of factors that would more appropriately identify them as OPD services. They are not independent services but are delivered as an integral part of the OPD service on the order of the physician who is providing the service; they are not typically provided under an established plan of care but on a direct physician order; they may be performed by nontherapists; and they frequently do not contribute to a rehabilitative process. For example, we note that therapists might be asked to provide a detailed documentation of patient weaknesses to be used by the physician to help identify or quantify a possible procedure-associated stroke or help with the mobilization of the patient after surgery in order to prevent blood clots. We note that these nontherapy services furnished by a therapist are limited to the immediate perioperative period, consistent with their inclusion as part of the larger service to deliver the device, and are distinct from

subsequent therapy services furnished under a therapy plan of care which serve to establish rehabilitative needs and begin the process of rehabilitation.

For that reason, when provided within this very limited context of a comprehensive service such as the implantation of an expensive device, we are proposing that services reported by therapy HCPCS codes, including costs associated with revenue codes 042X, 043X and 044X, would be considered to be adjunctive OPD services in support of the primary service when those services occur within the peri-operative period; that is, during the delivery of this comprehensive service that is bracketed by the OPD registration to initiate the service and the OPD discharge at the conclusion of the service. They do not constitute therapy services provided under a plan of care, are not subject to a therapy cap, if applied, and are not paid separately as therapy services.

• Inclusion of Additional Hospital Room and Board Revenue Centers in the Calculation of Covered Costs

We believe that the cost of the bed and room occupied by the patient, the cost of nursing services, and the cost of any necessary fluid and nutrition (board) are considered covered costs when incurred during the provision of an OPD service, that is, during the provision of the comprehensive service. Because we are able to assign all costs on the claim to the comprehensive service, we believe we have an opportunity to better capture costs by including these costs in our calculations even when they appear in certain revenue centers not usually used to report OPPS costs. Specifically, we are including costs reported with room, board, and nursing revenue codes 012X, 013x, 015X, 0160, 0169, 0200 through 0204, 0206 through 0209, 0210 through 0212, 0214, 0219, 0230 through 0234, 0239, 0240 through 0243, and 0249, as we believe these revenue centers are sometimes associated with the costs of room, nutrition, and nursing care provided during these comprehensive services.

• Inclusion of Hospital-Administered Drugs

We also are proposing to package all drugs provided to the beneficiary as part of the delivery of the comprehensive service except for those drugs separately paid through a transitional pass through payment. Intravenous drugs, for example, are OPPS services that are considered adjunctive to the primary procedure because the correct administration of the drug either promotes a beneficial outcome, such as the use of intravenous pain medications, or prevents possible complications, such as the use of intravenous blood pressure medications to temporarily replace oral blood pressure medications and reduce the risk of a sudden rise in blood pressure when a normal daily medication is stopped. We note that, in defining these packaged drugs, we are applying both our existing definitions of self-administered drugs (SADs) and our existing definition of drugs as supplies to the situation where the OPD service is a comprehensive service.

We are proposing that all medications provided by the hospital for delivery during a comprehensive service pursuant to a physician order, regardless of the route of administration, would be considered to be adjunctive supplies and therefore packaged as part of the comprehensive APC. We believe that the physician order demonstrates that the delivery of the medication by the hospital is necessary to avoid possible complications during the delivery of the comprehensive service, to ensure patient safety, and to ensure that the comprehensive service delivery is not compromised, and therefore the medication should be considered an adjunctive supply.

Therefore, we are proposing to consider all medications to be supplies that are adjunctive to the primary service if the medicines are ordered by the physician and supplied and delivered by the hospital for administration during the comprehensive service.

(c) Methodology

We calculated the proposed relative payment weights for these device-dependent comprehensive APCs by using relative costs derived from our standard process as described earlier in section II.A. of this proposed rule. Specifically, after converting charges to costs on the claims, we identified all claims containing one of the 136 HCPCS-defined procedures specified as constituting a comprehensive service. These claims were, by definition, classified as single major procedure claims. Any claims that contained more than one of these procedures were identified but were included in calculating the cost of the procedure that had the greatest cost when traditional HCPCS level accounting was applied. All other costs were summed to calculate the total cost of the comprehensive service, and statistics for those services were calculated in the usual manner. Claims with extreme costs were excluded in accordance with our usual process.

(d) Payments

We used the proposed relative payment weights of these device-dependent comprehensive services to calculate proposed payments following our standard methodology. The proposed payments for the HCPCS codes assigned to these proposed comprehensive APCs are included in Addendum B of this proposed rule (which is available via the Internet on the CMS Web site). We are proposing to assign a new status indicator, ''J1'' (OPD services paid through a comprehensive APC), to these device-dependent procedures. The claims processing system would be configured to make a single payment for the device-dependent comprehensive service whenever a HCPCS for one of these primary procedures appears on the claim. From a processing system perspective, all other adjunctive services except mammography, ambulance, and pass-through services would be conditionally packaged when a comprehensive service is identified on a claim. From our data, we have determined that multiple primary HCPCS codes occur together in 24 percent of these device-dependent claims but only rarely represent unrelated services. Having determined that having multiple unrelated device-dependent services is an uncommon event, we are proposing to pay only the largest comprehensive payment associated with a claim. However, the costs of all of these more extensive or additional services are included in the calculations of the relative payment weights for the comprehensive service, so the prospective payment includes payment for these occurrences.

(e) Impact of Proposed Comprehensive APCs for Device-Dependent Procedures

• Impact on Medicare Payments

Because these proposed device-dependent comprehensive APCs are entirely derived from existing services currently reported in Medicare claims, the proposed policy is effectively budget neutral in its impact on Medicare payments. We note that room, board, and nursing services have been covered costs in the delivery of outpatient services that require the patient to receive nursing services, occupy a bed for outpatient care, and maintain a controlled metabolic intake during a prolonged outpatient stay. Although we are including new revenue center costs for room and board when reported on these claims, we are including them to increase the accuracy of reporting not because they represent a new cost.

• Impact on APCs

Impact on Composite APCs. There is currently one device-dependent composite service in the OPPS, Cardiac Resynchronization Therapy, assigned to APC 0108. Because a comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, all of the elements of the composite service are included in the proposed new comprehensive service. Therefore, Cardiac Resynchronization Therapy would no longer be identified as a composite service but would be identified as a comprehensive service. All services currently assigned to APC 0108, including Cardiac Resynchronization Therapy, would be assigned to the proposed new comprehensive APC, with the proposed payment for CY 2014 identified in Addendum B of this proposed rule (which is available via the Internet on the CMS Web site).

Impact on Claims Used to Calculate Other APCs. Some costs reported on claims for device-dependent procedures may no longer be available to contribute to the calculations for other services through the pseudo-single process, described in section II.A. of this proposed rule. However, the loss of usable cost data for these services would be small because most of these services currently cannot be isolated as the ''single services'' that can be used in the cost calculation process. The exceptions are services such as EKGs and chest x-rays that occur in very high frequency across all types of encounters, and laboratory services and drugs, neither of which are calculated based on average cost. Finally, it is important to note that any loss is a small impact when compared against the 400,000 new claims that could now be used because of the establishment of the proposed comprehensive APC.

Impact on Device-Dependent APCs. The impact on current device-dependent APCs is described above in section II.A.2.d.(1) of this proposed rule. Comprehensive APC costs exceed the device-dependent procedure costs by an average of 11 percent, less than $1,000 per claim. The direct cost contribution of other OPPS services accounts for most of this increase, with laboratory tests contributing approximately $18 per claim (a 0.1 percent increase) and other non-OPPS payments contributing an additional $18 per claim. There is significant variation across comprehensive APCs, however, not only because the distribution of supporting services varies but also because the larger bundle allows a more complete incorporation of uncoded costs. Finally, the use of comprehensive APCs would allow the number of claims used to estimate costs for these services to almost triple from 233,000 to 649,000, increasing the accuracy of our cost estimates.

• Impact on Beneficiary Payments

Under the proposed comprehensive service APCs, instead of paying copayments for a number of separate services that are generally, individually subject to the copayment liability cap at section 1833(t)(8)(C)(i) of the Act, beneficiaries could expect to pay only a single copayment that is subject to the cap. This would likely reduce beneficiary overall liability for most of these claims.

(f) Summary of Proposal To Create Comprehensive APCs for High-Cost Device-Dependent Procedures

For CY 2014, we are proposing to create 29 comprehensive APCs to prospectively pay for device-dependent services associated with 136 HCPCS codes. We are proposing to treat all individually reported codes as representing components of the comprehensive service, making a single payment for the comprehensive service based on all charges on the claim, excluding only charges for services that cannot be covered by Medicare Part B or that are not payable under the OPPS. This would create a single all-inclusive payment for the claim that is subject to a single beneficiary copayment, up to the cap set at the level of the inpatient hospital deductible, as provided at section 1833(t)(8)(C)(i) of the Act.

As part of the proposed comprehensive APC, we are proposing to—

• Continue to package all services that were packaged in CY 2013.

• Unconditionally package all services elsewhere proposed for unconditional or conditional packaging for CY 2014.

• Package all adjunctive services provided during the delivery of the comprehensive service.

• Package room, board, and nursing costs necessary to deliver the outpatient service, regardless of whether or not the stay extends beyond a single calendar day.

• Package all hospital-administered drugs pursuant to a physician order, excluding pass-through drugs that are required to be separately paid by statute.

• Pay separately for mammography services and ambulance services as non-OPPS services, regardless of whether they are reported as part of a comprehensive service.

We are inviting public comment on this proposal.

f. Proposed Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care and as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for a full discussion of the development of the composite APC methodology (72 FR 66611 through 66614 and 66650 through 66652) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) for more recent background.

For CY 2014, we are proposing to continue our composite policies for extended assessment and management services, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, and multiple imaging services, as discussed below. We are proposing to discontinue and supersede the cardiac resynchronization therapy composite APC by our proposed comprehensive APC 0108, as discussed in section II.A.2.e of this proposed rule.

(1) Extended Assessment and Management Composite APCs (APCs 8002 and 8003)

(a) Background

Beginning in CY 2008, we included composite APC 8002 (Level I Extended Assessment and Management Composite) and composite APC 8003 (Level II Extended Assessment and Management Composite) in the OPPS to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (an extended visit). In most of these circumstances, observation services are supportive and ancillary to the other services provided to a patient. From CY 2008 through CY 2013, in the circumstances when observation care is provided in conjunction with a high level visit, critical care, or direct referral and is an integral part of a patient's extended encounter of care, payment is made for the entire care encounter through one of the two composite APCs as appropriate. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163 through 74165) for a full discussion of this longstanding policy for CY 2013 and prior years.

For CY 2014, we are proposing to modify our longstanding policy to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur. Primarily, we are proposing to allow any visit furnished by a hospital in conjunction with observation services of substantial duration to qualify for payment through the Extended Assessment and Management (EAM) Composite APC. Also, rather than recognizing two levels of EAM Composite APCs, we are proposing to create a new composite APC entitled, ''Extended Assessment and Management (EAM) Composite,'' (APC 8009) to provide payment for all qualifying extended assessment and management encounters. These proposals are discussed in greater detail below.

(b) Proposed Payment for Extended Assessment and Management Services

As discussed in section VII. of this proposed rule, we are proposing to no longer recognize five distinct visit levels for clinic visits and emergency department visits based on the existing HCPCS E/M codes, and instead recognize three new alphanumeric HCPCS codes for each visit type. Currently, the payment criteria for the EAM composite APCs 8002 and 8003 include a high level visit represented by HCPCS code 99205, 99215, 99284, 99285, or G0304; critical care represented by CPT code 99281; or direct referral represented by HCPCS code G0379 provided in conjunction with observation care represented by HCPCS code G0378. In light of the proposal to no longer differentiate visit payment levels, and the fact that the current high level visit codes (HCPCS codes 99205, 99215, 99284, 99285 and G0304) would no longer be recognized under the OPPS, it would no longer be feasible to continue with our current payment criteria for the EAM composite APCs 8002 and 8003 for CY 2014. Therefore, to ensure that we continue to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur, for CY 2014, we are proposing to provide payment for the entire care encounter through proposed new EAM Composite APC 8009 when observation care is provided in conjunction with a visit, critical care, or direct referral and is an integral part of a patient's extended encounter of care. Specifically, for CY 2014, we are proposing to provide EAM composite APC payment, through a newly created composite APC in circumstances when a clinic or ED visit, identified by one of the three new alphanumeric HCPCS codes proposed in section VII. of this proposed rule, is accompanied by observation care of substantial duration on a claim. We would no longer recognize APC 8002 or APC 8003. The specific criteria we are proposing to be met for the proposed new EAM composite APC to be paid is provided below in the description of the claims that we are proposing to select for the calculation of the proposed CY 2016 mean costs for this composite APC.

We are proposing to calculate the mean costs for the proposed new EAM composite APC (APC 8009) for CY 2014 using CY 2012 single and ''pseudo'' single procedure claims that meet each of the following criteria:

- The claim does not contain a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and ''pseudo'' single claims, we assured that they would not contain a code for a service with status indicator ''T'' on the same date of service.);
- The claim contains 8 or more units of HCPCS code G0378 (Observation services, per hour); and
- The claim contains one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as G0378; or CPT code 99201 (Office or other outpatient visit for the evaluation and management of a new patient (Level 1)); CPT code 99202 (Office or other outpatient visit for the evaluation and management of a new patient (Level 2)); CPT code 99203 (Office or other outpatient visit for the evaluation and management of a new patient (Level 3)); CPT code 99204 (Office or other outpatient visit for the evaluation and management of a new patient (Level 4)); CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)); CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient (Level 1)); CPT code 99212 (Office or other outpatient visit for the evaluation and management of an established patient (Level 2)); CPT code 99213 (Office or other outpatient visit for the evaluation and management of an established patient (Level 3)); CPT code 99214 (Office or other outpatient visit for the evaluation and management of an established patient (Level 4)); CPT code 99215 (Office or other outpatient visit for the evaluation and management of an established patient (Level 5)); CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)); or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); or CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) provided on the same date of service or 1 day before the date of service for HCPCS code G0378.

The proposed CY 2014 cost resulting from this methodology for the proposed new EAM composite APC (APC 8009) is approximately $1,357, which was calculated from 318,265 single and ''pseudo'' single claims that met the required criteria.

When hospital claims data for the CY 2014 proposed clinic and ED visit codes becomes available, we are proposing to

calculate the mean costs for the proposed new EAM composite APC (APC 8009) for CY 2016 using CY 2014 single and ''pseudo'' single procedure claims that meet each of the following criteria:

- The claims do not contain a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and ''pseudo'' single claims, we ensure that they would not contain a code for a service with status indicator ''T'' on the same date of service.);
- The claims contain 8 or more units of HCPCS code G0378 (Observation services, per hour); and
- The claims contain one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as G0378; or CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or newly proposed alphanumeric Level II HCPCS code GXXXA (Type A ED visit); newly proposed alphanumeric Level II HCPCS code GXXXB (Type B ED visit); or newly proposed alphanumeric Level II HCPCS code GXXXC (Clinic visit) provided on the same date of service or 1 day before the date of service for HCPCS code G0378.

(2) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the composite treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex), which are generally present together on claims for the same date of service in the same operative session. In order to base payment on claims for the most common clinical scenario, and to further our goal of providing payment under the OPPS for a larger bundle of component services provided in a single hospital encounter, beginning in CY 2008, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We based the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPPS payment for LDR prostate brachytherapy and a detailed description of how we developed the LDR prostate brachytherapy composite APC.

For CY 2014, we are proposing to continue to pay for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2013. That is, we are proposing to use CY 2012 claims on which both CPT codes 55875 and 77778 were billed on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2013 practice, we are proposing not to use the claims that meet these criteria in the calculation of the costs for APC 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) and APC 0651 (Complex Interstitial Radiation Source Application), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We are proposing to continue to calculate the costs for APCs 0163 and 0651 using single and ''pseudo'' single procedure claims. We believe that this composite APC contributes to our goal of creating hospital incentives for efficiency and cost containment, while providing hospitals with the most flexibility to manage their resources. We also continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate cost upon which to base the composite APC payment rate.

Using a partial year of CY 2012 claims data available for this CY 2014 OPPS/ASC proposed rule, we were able to use 1,487 claims that contained both CPT codes 55875 and 77778 to calculate the cost upon which the proposed CY 2014 payment for composite APC 8001 is based. The proposed cost for composite APC 8001 for CY 2014 is approximately $4,340.

(3) Cardiac Electrophysiologic Evaluation and Ablation Composite APC (APC 8000)

Effective January 1, 2008, we established APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite) to pay for a composite service made up of at least one specified electrophysiologic evaluation service and one specified electrophysiologic ablation service. Correctly coded claims for these services often include multiple codes for component services that are reported with different CPT codes and that, prior to CY 2008, were always paid separately through different APCs (specifically, APC 0085 (Level II Electrophysiologic Evaluation), APC 0086 (Ablate Heart Dysrhythm Focus), and APC 0087 (Cardiac Electrophysiologic Recording/Mapping)). Calculating a composite APC for these services allowed us to utilize many more claims than were available to establish the individual APC costs for these services, and advanced our stated goal of promoting hospital efficiency through larger payment bundles. In order to calculate the cost upon which the payment rate for composite APC 8000 is based, we used multiple procedure claims that contained at least one CPT code from Group A for evaluation services and at least one CPT code from Group B for ablation services reported on the same date of service on an individual claim. Table 9 in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66656) identified the CPT codes that are assigned to Groups A and B. For a full discussion of how we identified the Group A and Group B procedures and established the payment rate for the cardiac electrophysiologic evaluation and ablation composite APC, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66655 through 66659). Where a service in Group A is furnished on a date of service that is different from the date of service for a CPT code in Group B for the same beneficiary, payments are made under the appropriate single procedure APCs and the composite APC does not apply.

Subsequent to the publication of the CY 2013 OPPS/ASC proposed rule, the AMA's CPT Editorial Panel created five new CPT codes describing cardiac electrophysiologic evaluation and ablation services, effective January 1, 2013. These five new codes are:

- CPT code 93653 (Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia

with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry);

- CPT code 93654 (Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed);
- CPT code 93655 (Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure));
- CPT code 93656 (Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation); and
- CPT code 93657 (Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)).

The CPT Editorial Panel also deleted two electrophysiologic ablation codes, CPT code 93651 (Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combination) and CPT code 93652 (Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia), effective January 1, 2013.

As we described in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68425), new CPT codes 93653, 93654, and 93656 are primary electrophysiologic services that encompass evaluation as well as ablation, while new CPT codes 93655 and 93657 are add-on codes. Because CPT codes 93653, 93654, and 93656 already encompass both evaluation and ablation services, we assigned them to composite APC 8000 with no further requirement to have another electrophysiologic service from either Group A or Group B furnished on the same date of service, and we assigned them interim status indicator ''Q3'' (Codes that may be paid through a composite APC) in Addendum B to the CY 2013 OPPS/ASC final rule with comment period. To facilitate implementing this policy, we assigned CPT codes 93653, 93654, and 93656 to a new Group C, which is paid at the composite APC 8000 payment rate. (We noted that we will use single and ''pseudo'' single claims for CPT codes 93653, 93654, and 93656 when they become available for calculating the costs upon which the payment rate for APC 8000 will be based in future ratesetting.) Because CPT codes 93655 and 93657 are dependent services that may only be performed as ancillary services to the primary CPT codes 93653, 93654, and 93656, we believed that packaging CPT codes 93655 and 93657 with the primary procedures is appropriate, and we assigned them interim status indicator ''N.'' Because the CPT Editorial Panel deleted CPT codes 93651 and 93652, effective January 1, 2013, we deleted them from the Group B code list, leaving only CPT code 93650 (Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement) in Group B.

As is our usual practice for new CPT codes that were not available at the time of the proposed rule, our treatment of new CPT codes 93653, 93654, 93655, 93656, and 93657 was open to public comment for a period of 60 days following the publication of the CY 2013 OPPS/ASC final rule with comment period.

For CY 2014, we are proposing to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2013. We also are proposing to continue the new Group C methodology we first established for CY 2013, described above, in response to the CPT Editorial Panel's creation of primary CPT codes 93653, 93654, and 93656. We continue to believe that the cost for cardiac electrophysiologic evaluation and ablation services calculated from a high volume of correctly coded multiple procedure claims would result in an accurate and appropriate proposed payment for these services when at least one evaluation service is furnished during the same clinical encounter as at least one ablation service. Consistent with our practice since CY 2008, we are proposing not to use the claims that met the composite payment criteria in the calculation of the costs for APC 0085, to which the CPT codes in both Groups A and B for composite APC 8000 are otherwise assigned. We are proposing that the costs for APC 0085 would continue to be calculated using single procedure claims. For CY 2014, using a partial year of CY 2012 claims data available for this CY 2014 OPPS/ASC proposed rule, we were able to use 15,817 claims containing a combination of Group A and Group B CPT codes (Group C was not effective until January 1, 2013) to calculate a proposed cost of approximately $13,402 for composite APC 8000.

Table 6 below lists the proposed groups of procedures upon which we would base composite APC 8000 for CY 2014.

TABLE 6—PROPOSED GROUPS OF CARDIAC ELECTROPHYSIOLOGIC EVALUATION AND ABLATION PROCEDURES UPON WHICH COMPOSITE APC 8000 IS BASED

Codes Used in Combinations: At least one in Group A and one in Group B, or at least one in Group C	CY 2014 CPT Code	Proposed single code CY 2014 APC	Proposed CY 2014 SI (composite)
Group A			
Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia	93619	0085	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording	93620	0085	Q3
Group B			
Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	93650	0085	Q3
Group C			
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	93653	8000	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed	93654	8000	Q3
Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation	93656	8000	Q3

(4) Mental Health Services Composite APC (APC 0034)

For CY 2104, we are proposing to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health treatments. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 to 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

We are proposing that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one date of service based on the payment rates associated with the APCs for the individual services exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be assigned to APC 0034 (Mental Health Services Composite). Specifically, we are proposing to continue to set the payment rate for APC 0034 at the same payment rate that we are proposing to establish for APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs), which is the maximum partial hospitalization per diem payment rate for a hospital and proposing that the hospital would continue to be paid one unit of APC 0034. Under this policy, the I/OCE would continue to determine whether to pay for these specified mental health services individually or to make a single payment at the same payment rate established for APC 0176 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program represent the most resource-intensive of all outpatient mental health treatments. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

(5) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital bills more than one imaging procedure within an imaging family on the same date of service, in order to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 6 of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68253 through 68257).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included in the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for composite APC payment, as well as any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2014, we are proposing to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. The proposed CY 2014 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) are based on costs calculated from a partial year of CY 2012 claims available for this CY 2014 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims with more than one procedure within the same family on a single date of service). To calculate the proposed costs, we used the same methodology that we used to calculate the final CY 2012 and CY 2013 costs for these composite APCs, as described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74169). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC costs, pursuant to our established methodology (76 FR 74169), are identified by asterisks in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site) and are discussed in more detail in section II.A.1.b. of this proposed rule.

We were able to identify approximately 0.8 million ''single session''' claims out of an estimated 1.5 million potential composite cases from our ratesetting claims data, more than half of all eligible claims, to calculate the proposed CY 2014 costs for the multiple imaging composite APCs.

Table 7 below lists the proposed HCPCS codes that would be subject to the multiple imaging composite policy and their respective families and approximate composite APC costs for CY 2014. We note that the proposed costs calculated for many imaging APCs, including the multiple imaging composite APCs, have changed significantly from the costs calculated for the CY 2013 OPPS/ASC final rule with comment period for these APCs as a result of the proposed adoption of the new MRI and CT cost centers, as discussed in section II.A.1.c. of this proposed rule.

TABLE 7—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Proposed CY 2014 APC 8004 (ultrasound composite)	Proposed CY 2014 approximate APC cost = $322
Family 1—Ultrasound	
76604	Us exam, chest.
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/Doppler.
76831	Echo exam, uterus.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.
Proposed CY 2014 APC 8005 (CT and CTA without contrast composite)*	Proposed CY 2014 approximate APC cost = $304
Family 2—CT and CTA with and without Contrast	
70450	Ct head/brain w/o dye.
70480	Ct orbit/ear/fossa w/o dye.
70486	Ct maxillofacial w/o dye.
70490	Ct soft tissue neck w/o dye.
71250	Ct thorax w/o dye.
72125	Ct neck spine w/o dye.
72128	Ct chest spine w/o dye.
72131	Ct lumbar spine w/o dye.
72192	Ct pelvis w/o dye.

TABLE 7—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

73200	Ct upper extremity w/o dye.
73700	Ct lower extremity w/o dye.
74150	Ct abdomen w/o dye.
74261	Ct colonography, w/o dye.
74176	Ct angio abd & pelvis.
Proposed CY 2014 APC 8007 (CT and CTA with Contrast composite)	Proposed CY 2014 approximate APC cost = $522
70487	Ct maxillofacial w/dye.
70460	Ct head/brain w/dye.
70470	Ct head/brain w/o & w/dye.
70481	Ct orbit/ear/fossa w/dye.
70482	Ct orbit/ear/fossa w/o&w/dye.
70488	Ct maxillofacial w/o & w/dye.
70491	Ct soft tissue neck w/dye.
70492	Ct sft tsue nck w/o & w/dye.
70496	Ct angiography, head.
70498	Ct angiography, neck.
71260	Ct thorax w/dye.
71270	Ct thorax w/o & w/dye.
71275	Ct angiography, chest.
72126	Ct neck spine w/dye.
72127	Ct neck spine w/o & w/dye.
72129	Ct chest spine w/dye.
72130	Ct chest spine w/o & w/dye.
72132	Ct lumbar spine w/dye.
72133	Ct lumbar spine w/o & w/dye.
72191	Ct angiograph pelv w/o&w/dye.
72193	Ct pelvis w/dye.
72194	Ct pelvis w/o & w/dye.
73201	Ct upper extremity w/dye.
73202	Ct uppr extremity w/o&w/dye.
73206	Ct angio upr extrm w/o&w/dye.
73701	Ct lower extremity w/dye.
73702	Ct lwr extremity w/o&w/dye.
73706	Ct angio lwr extr w/o&w/dye.
74160	Ct abdomen w/dye.
74170	Ct abdomen w/o & w/dye.
74175	Ct angio abdom w/o & w/dye.
74262	Ct colonography, w/dye.
75635	Ct angio abdominal arteries.
74177	Ct angio abd&pelv w/contrast.
74178	Ct angio abd & pelv 1+ regns.

* If a ''without contrast'' CT or CTA procedure is performed during the same session as a ''with contrast'' CT or CTA procedure, the I/OCE will assign APC 8006 rather than APC 8005.

Proposed CY 2014 APC 8007 (MRI and MRA without Contrast composite) *	Proposed CY 2014 approximate APC cost = $612
Family 3—MRI and MRA with and without Contrast	
70336	Magnetic image, jaw joint.
70540	Mri orbit/face/neck w/o dye.
70544	Mr angiography head w/o dye.
70547	Mr angiography neck w/o dye.
70551	Mri brain w/o dye.
70554	Fmri brain by tech.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
72195	Mri pelvis w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.
74181	Mri abdomen w/o dye.
75557	Cardiac mri for morph.
75559	Cardiac mri w/stress img.
C8901	MRA w/o cont, abd.
C8904	MRI w/o cont, breast, uni.
C8907	MRI w/o cont, breast, bi.
C8910	MRA w/o cont, chest.

TABLE 7—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

C8913	MRA w/o cont, lwr ext.
C8919	MRA w/o cont, pelvis.
C8932	MRA, w/o dye, spinal canal.
C8935	MRA, w/o dye, upper extr.
Proposed CY 2014 APC 8008 (MRI and MRA with contrast composite)	Proposed CY 2014 approximate APC cost = $908
70549	Mr angiograph neck w/o&w/dye.
70542	Mri orbit/face/neck w/dye.
70543	Mri orbt/fac/nck w/o & w/dye.
70545	Mr angiography head w/dye.
70546	Mr angiograph head w/o&w/dye.
70547	Mr angiography neck w/o dye.
70548	Mr angiography neck w/dye.
70552	Mri brain w/dye.
70553	Mri brain w/o & w/dye.
71551	Mri chest w/dye.
71552	Mri chest w/o & w/dye.
72142	Mri neck spine w/dye.
72147	Mri chest spine w/dye.
72149	Mri lumbar spine w/dye.
72156	Mri neck spine w/o & w/dye.
72157	Mri chest spine w/o & w/dye.
72158	Mri lumbar spine w/o & w/dye.
72196	Mri pelvis w/dye.
72197	Mri pelvis w/o & w/dye.
73219	Mri upper extremity w/dye.
73220	Mri uppr extremity w/o&w/dye.
73222	Mri joint upr extrem w/dye.
73223	Mri joint upr extr w/o&w/dye.
73719	Mri lower extremity w/dye.
73720	Mri lwr extremity w/o&w/dye.
73722	Mri joint of lwr extr w/dye.
73723	Mri joint lwr extr w/o&w/dye.
74182	Mri abdomen w/dye.
74183	Mri abdomen w/o & w/dye.
75561	Cardiac mri for morph w/dye.
75563	Card mri w/stress img & dye.
C8900	MRA w/cont, abd.
C8902	MRA w/o fol w/cont, abd.
C8903	MRI w/cont, breast, uni.
C8905	MRI w/o fol w/cont, brst, un.
C8906	MRI w/cont, breast, bi.
C8908	MRI w/o fol w/cont, breast,.
C8909	MRA w/cont, chest.
C8911	MRA w/o fol w/cont, chest.
C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye, spinal canal.
C8933	MRA, w/o&w/dye, spinal canal.
C8934	MRA, w/dye, upper extremity.
C8936	MRA, w/o&w/dye, upper extr.

* If a ''without contrast'' MRI or MRA procedure is performed during the same session as a ''with contrast'' MRI or MRA procedure, the I/OCE will assign APC 8008 rather than APC 8007.

3. Proposed Changes to Packaged Items and Services

a. Background

Like other prospective payment systems, the OPPS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a specific service or bundle of specific services for a particular patient. However, with the exception of outlier cases, overall payment is adequate to ensure access to appropriate care. The OPPS packages payment for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. Our packaging policies support our strategic goal of using larger payment bundles to maximize hospitals' incentives to provide care in the most efficient matter. In addition, the OPPS packages payment for multiple interrelated items and services into a single payment, regardless of whether dedicated CPT or HCPCS codes describe the services or the cost of the individual items and services. For example, where there are a variety of devices, drugs, items, supplies, etc. that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely

use a more expensive item, which often results if separate payment is provided for the items. This encourages hospitals that are spending more per case than the payment they received to review their service patterns to ensure that they furnish services as efficiently as possible. Similarly, we believe that separate payment for items and services heightens the hospital's focus on the payment for individual services, rather than the efficient delivery of those services.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. Most, but not necessarily all, items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2008 OPPS/ASC proposed rule (72 FR 42628) and the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580).

We use the term ''dependent service'' to refer to the HCPCS codes that represent services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality. We use the term ''primary service'' to refer to the HCPCS codes that represent the primary therapeutic or diagnostic modality into which we package payment for the dependent service. Over the last decade, we have refined our understanding and implementation of the OPPS and have packaged numerous services that we originally paid as primary services, and as we consider the development of larger payment groups that more broadly reflect services provided in an encounter or episode of care, we may propose to expand these packaging policies as they apply to services that we may currently pay as primary services.

We assign status indicator ''N'' to those HCPCS codes of dependent services that we believe are always integral to the performance of the primary modality. Therefore, we always package their costs into the costs of the separately paid primary services with which they are billed. Services assigned to status indicator ''N'' are unconditionally packaged. The following description of the conditional packaging status indicators reflects our proposal to discontinue the use of status indicator ''X,'' which we discuss below. We assign status indicator ''Q1'' (STV-Packaged Codes), ''Q2'' (T-Packaged Codes), or ''Q3'' (Codes that may be paid through a composite APC) to each conditionally packaged HCPCS code. An STV-packaged code describes a HCPCS code whose payment is packaged with one or more separately paid primary services with the status indicator of ''S,'' ''T,'' or ''V'' furnished in the hospital outpatient encounter. A T-packaged code describes a code whose payment is only packaged with one or more separately paid surgical procedures with the status indicator of ''T'' that are provided during the hospital outpatient encounter. STV-packaged codes and T-packaged codes are paid separately in those uncommon cases when they do not meet their respective criteria for packaged payment. STV-packaged codes and T-packaged codes are conditionally packaged. We refer readers to the discussion of proposed CY 2014 OPPS payment status and comment indicators in section XI. of this proposed rule and Addendum D1, which is available via the Internet on the CMS Web site, for a complete listing of status indicators and the meaning of each status indicator.

Hospitals include HCPCS codes and charges for packaged services on their claims, and the estimated costs associated with those packaged services are then added to the costs of separately payable procedures on the same claims to establish prospective payment rates. We encourage hospitals to report all HCPCS codes that describe packaged services provided, unless the CPT Editorial Panel or CMS provides other specific guidance. The appropriateness of the OPPS payment rates depends on the quality and completeness of the claims data that hospitals submit for the services they furnish to Medicare beneficiaries.

In addition to the packaged items and services listed in 42 CFR 419.2(b), in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66610 through 66659), we adopted the packaging of payment for items and services in seven categories with the primary diagnostic or therapeutic modality to which we believe these items and services are typically ancillary and supportive. The seven categories are: (1) Guidance services; (2) image processing services; (3) intraoperative services; (4) imaging supervision and interpretation services; (5) diagnostic radiopharmaceuticals; (6) contrast media; and (7) observation services. We specifically chose these categories of HCPCS codes for packaging because we believe that the items and services described by the codes in these categories are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. In addition, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634), we packaged products described as implantable biologicals. As discussed below, we are proposing to add each of these categories of packaged items and services that were packaged beginning in CYs 2008 and 2009, along with newly proposed packaged items and services for CY 2014 as described below to the OPPS packaging regulation at § 419.2(b). Packaging under the OPPS also includes composite APCs, which are described in section II.A.2.f. of this proposed rule.

b. Basis for Proposed New Packaging Policies for CY 2014

As discussed above, the OPPS is a prospective payment system. It is not intended to be a fee schedule, in which separate payment is made for each coded line item. However, the OPPS is currently a prospective payment system that packages some items and services but not others. Payment for some items and services in the OPPS is according to the principles of a prospective payment system, while the payment for other items and services is more like that of a fee schedule. Our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided in the OPPS to determine which OPPS services can be packaged to achieve the objective of

advancing the OPPS as a prospective payment system.

Therefore, as we did in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66610 through 66659), we have examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment of the primary service they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) to see whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In general, we are proposing to package the costs of selected HCPCS codes into payment for services reported with other HCPCS codes where we believe that one code reported an item or service that was integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by another HCPCS code. Below we discuss categories and classes of items and services that we are proposing to package beginning in CY 2014. In several cases, we are proposing that services be conditionally packaged so that if they are provided without other services, there will be a separate payment for the service. The proposed policies detailed below are not exhaustive, and we expect to continue to review the OPPS and consider additional packaging policies in the future.

c. Proposed New Packaging Policies for CY 2014

(1) Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure

In the OPPS, we currently unconditionally package the following six categories of drugs, biologicals, and radiopharmaceuticals (unless temporary pass-through status applies): (1) Those with per day costs at or below the packaging threshold (discussed further in section V.B.2. of this proposed rule); (2) diagnostic radiopharmaceuticals; (3) contrast agents; (4) anesthesia drugs; (5) drugs used as supplies according to § 419.2(b)(4)); and (6) implantable biologicals. For CY 2014, we reviewed all of the drugs, biologicals, and radiopharmaceuticals administered in the hospital outpatient setting to identify categories or classes of drugs, biologicals, and radiopharmaceuticals that either should be packaged according to existing packaging policies or should be packaged as a logical expansion of existing OPPS packaging policies for drugs, biologicals, and radiopharmaceuticals.

Currently, two of the categories of drugs, biologicals, and radiopharmaceuticals that are packaged in the OPPS (contrast agents and diagnostic radiopharmaceuticals) have a common characteristic—they both describe products that function as supplies that are used in a diagnostic test or procedure. Although in the past we identified these specific categories of drugs, biologicals, and radiopharmaceuticals as packaged after the expiration of pass-through status, we recognize that they actually represent subcategories of a broader category of drugs, biologicals, and radiopharmaceuticals that should be packaged in the OPPS according to OPPS packaging principles: drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. In particular, we are referring to drugs, biologicals, and radiopharmaceuticals that function as supplies as a part of a larger, more encompassing service or procedure, namely, the diagnostic test or procedure in which the drug, biological, or radiopharmaceutical is employed. Because diagnostic radiopharmaceuticals and contrast agents represent specific examples of a broader category of drugs, biologicals, or radiopharmaceuticals that may function as a supply that is integral and supportive to a diagnostic test or procedure, we are proposing to unconditionally package drugs, biologicals, and radiopharmaceuticals that function as a supply when used in a diagnostic test or procedure, except when the drug, biological, or radiopharmaceutical has pass-through status.

A diagnostic test or procedure is defined as any kind of test or procedure performed to aid in the diagnosis, detection, monitoring, or evaluation of a disease or condition. A diagnostic test or procedure also includes tests or procedures performed to determine which treatment option is optimal. A diagnostic test or procedure can have multiple purposes, but at least one purpose must be diagnostic. We are proposing to revise the regulations at § 419.2(b) to specify that any drugs, biologicals, and radiopharmaceuticals that function as supplies when used in diagnostic tests or procedures will be packaged as supplies in the OPPS, except when pass-through status applies. This proposed broader category of packaged drugs, biologicals, and radiopharmaceuticals includes the currently packaged categories of contrast agents and diagnostic radiopharmaceuticals when used in a diagnostic test or procedure. We have identified specific drugs that function as supplies when used in a diagnostic test or procedure that fall under this proposed packaging policy, and discuss these drugs below.

(a) Stress Agents

Our review of OPPS drugs identified pharmacologic stress agents (''stress agents'') as a class of drugs that is described by the proposed packaged category of drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. Stress agents are a class of drugs that are used in diagnostic tests to evaluate certain aspects of cardiac function. In many cases, these agents are used in patients who are unable to perform an exercise stress test, which typically precedes additional diagnostic testing. The primary diagnostic test in which these agents are used is myocardial perfusion imaging (MPI), which is the highest cost nuclear medicine procedure in the OPPS, with OPPS payments exceeding $800 million in CY 2012. Approximately 96 percent of MPI is billed with CPT code 78452. Stress agents include the following drugs described by these HCPCS codes: HCPCS codes J0152 (Injection, adenosine for diagnostic use, 30 mg); J1245 (Injection, dipyridamole, per 10 mg); J1250 (Injection, dobutamine hydrochloride, per 250 mg); and J2785 (Injection, regadenoson, 0.1 mg). For CY 2013, HCPCS codes J1245 and J1250 are packaged in the OPPS, and J0152 and J2785 are separately paid. OPPS payments for the two separately payable stress agents totaled approximately $111 million in CY 2012.

Beginning in CY 2014, we are proposing to package all stress agents that function as supplies into the diagnostic tests or procedures in which they are employed, consistent with the policy proposed above. The primary service in which stress agents are employed is MPI. MPI with stress encompasses the imaging service, the stress test, and either exercise to induce stress or the administration of a pharmacologic stress agent. The various combinations of items and services that constitute MPI with stress are depicted in the table below, which includes the CY 2013 separate payment rates versus the proposed CY 2014 packaged payment rate for MPI.

TABLE 8—CY 2013 SEPARATE PAYMENT VERSUS CY 2014 PROPOSED PACKAGED PAYMENT FOR MPI

Service or supply	CY 2013 Separate payment for MPI components	CY 2013 Separate payment for MPI components	CY 2013 Separate payment for MPI components	CY 2013 Separate payment for MPI components	CY 2014 Proposed packaged payment for MPI
78452	$672	$672	$672	$672	$1,235
93017	$178	$178	$178	$178	P €
Exercise or Stress Agent ¥	Exercise–$0	J1245–P	J2785–$215	* J0152–$219	P
Radiopharmaceutical	P	P	P	P	P
Total	$850	$850	$1,065	$1,069	$1,235

P = Packaged.
€ The stress test described by CPT code 93017 is proposed to be conditionally packaged as a result of the proposal described below to conditionally package ancillary services.
¥ April 2013 ASP Drug Pricing File.
* 70 kg patient.

The proposed CY 2014 payment rate for MPI with the stress test, stress agent, and diagnostic radiopharmaceutical packaged into MPI is 14 percent higher than the sum of the CY 2013 payments for separately paid MPI, a separately paid stress test, and either of the two separately paid stress agents.

(b) Hexaminolevulinate Hydrochloride (Cysview®)—HCPCS Code C9275

Cysview is a drug for which pass-through status expired on December 31, 2012. Beginning in CY 2013, Cysview was unconditionally packaged in the OPPS as a contrast agent (77 FR 68364). The indications and usage of Cysview as listed in the FDA-approved label are as follows: ''Cysview is an optical imaging agent indicated for use in the cystoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. Cysview is used with the Karl Storz D-Light C Photodynamic Diagnostic (PDD) system to perform cystoscopy with the blue light setting (Mode 2) as an adjunct to the white light setting (Mode 1).''

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 42672), we described contrast agents as follows: ''Contrast agents are generally considered to be those substances introduced into or around a structure that, because of the differential absorption of x-rays, alteration of magnetic fields, or other effects of the contrast medium in comparison with surrounding tissues, permit visualization of the structure through an imaging modality. The use of certain contrast agents is generally associated with specific imaging modalities, including x-ray, computed tomography (CT), ultrasound, and magnetic resonance imaging (MRI), for purposes of diagnostic testing or treatment.''

Upon reexamining this description of contrast agents and considering our prior application of this description to specific compounds, we believe that contrast agents should include those compounds that are used with the imaging modalities x-ray, computed tomography (CT), ultrasound, magnetic resonance imaging (MRI), and other related modalities that could represent advancements of these modalities. Based on the indications and usage described above for Cysview, we do not believe that Cysview is best described as a contrast agent. Rather, we believe Cysview is more appropriately described as a drug used in a procedure to diagnose bladder cancer.

As discussed above, we are proposing a new policy to package all drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. Cysview is a drug that functions as a supply when used in a diagnostic test or procedure for the purpose of the ''detection of non-muscle invasive papillary cancer of the bladder.'' Therefore, as a drug that functions as a supply when used in a diagnostic test or procedure, we are proposing to package Cysview for CY 2014 under the OPPS. Cysview is currently assigned to status indicator ''N'' for CY 2013, and under this proposal, the status indicator assignment of ''N'' would continue for CY 2014.

(2) Drugs and Biologicals That Function as Supplies or Devices When Used in a Surgical Procedure

Since the inception of the OPPS we have packaged medical devices, medical and surgical supplies, and surgical dressings into the related procedure under § 419.2(b)(4). Medical and surgical supplies are a broad category of items used in the hospital outpatient setting. Supplies is a large category of items that typically are either for single patient use or have a shorter life span in use than equipment. Supplies include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in the hospital outpatient setting, including certain implantable medical devices. We consider implantable medical devices to be integral to, dependent on, and supportive to a surgical implantation procedure. For further discussion, we refer readers to the CY 2000 OPPS final rule (65 FR 18443 through 18444). Packaged supplies can include certain drugs, biologicals, and radiopharmaceuticals. Packaged supplies in the OPPS also include implantable biologicals, which are packaged because they function as implantable devices which, as noted above, are considered to be a type of supply in the OPPS. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634) for a more detailed discussion. We believe that the existing packaging policy for implantable biologicals represents an example of a broader category of drugs and biologicals that should be packaged in the OPPS according to longstanding regulations and existing policies: drugs and biologicals that function as supplies or devices in a surgical procedure. Therefore, beginning in the CY 2014 OPPS, we are proposing to unconditionally package all drugs and biologicals that function as supplies or devices in a surgical procedure, following the current policy that is applied to implantable biologicals.

A class of products that we treat as biologicals in the OPPS that is described by the proposed packaging category of drugs and biologicals that function as supplies or devices in a surgical procedure is skin substitutes. The term ''skin substitutes'' refers to a category of products that are most commonly used in outpatient settings for the treatment

of diabetic foot ulcers and venous leg ulcers. Although the term ''skin substitute'' has been adopted to refer to this category of products in certain contexts, these products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are various types of wound dressings that, through various mechanisms of action, stimulate the host to regenerate lost tissue and replace the wound with functional skin. We refer readers to the ''Skin Substitutes for Treating Chronic Wounds Technology Assessment Report at ES–2'' which is available on the AHRQ Web site at: *http://www.ahrq.gov/research/findings/ta/skinsubs/HCPR0610_skinsubst-final.pdf*. Currently, available skin substitutes are regulated by the FDA as either medical devices (and classified as wound dressings) or as human cell, tissue, and cellular and tissue-based products (HCT/Ps) under section 361 of the Public Health Service Act. The different skin substitutes are applied to a wound during a surgical procedure described by CPT codes in the range 15271 through 15278. To be properly performed, every surgical procedure in this CPT code range requires the use of at least one skin substitute product. These surgical procedures include preparation of the wound and application of the skin substitute product through suturing or various other techniques. Currently skin substitutes are separately paid in the OPPS as if they are biologicals according to the ASP methodology and are subject to the drug and biological packaging threshold.

Because a skin substitute must be used to perform any of the procedures described by a CPT code in the range 15271 through 15278, and conversely because it is the surgical procedure of treating the wound and applying a covering to the wound that is the independent service, skin substitute products serve as a necessary supply for these surgical repair procedures. In addition, many skin substitutes are classified by the FDA as wound dressings, which make them the same or similar to surgical dressings that are packaged under § 419.2(b)(4). Finally, implantable biological products are very similar to (and in some instances the same as) skin substitute products, except that the clinical applications for implantable biologicals are typically an internal surgery versus the application to a wound for a skin substitute. Some products had or have dual uses as both skin substitutes and implantable biologicals, which underscores the similarity of these sometimes overlapping classes of products. Implantable biologicals and skin substitutes both function as supplies or devices that are used in surgical procedures and, therefore, should be packaged with the surgical procedure in which the products are used. Since CY 2009, we have packaged implantable biologicals and we are proposing to package skin substitutes with their associated surgeries beginning in CY 2014. We see no reason to distinguish skin substitutes from implantable biologicals for OPPS packaging purposes based on the clinical application of individual products. Therefore, we are proposing to unconditionally package skin substitutes into their associated surgical procedures. Packaging payment for these skin substitutes into the APC payment for the related surgical procedures also would result in a total prospective payment that is more reflective of the average resource costs of the procedures because prices for these products vary significantly from product to product. Packaging these products also would promote more efficient resource use by hospitals and would be more consistent with the treatment of similar products under the OPPS. We are proposing to revise the regulations at § 419.2(b)(4) to include skin substitutes as an example of a packaged surgical supply. Pass-through status would still be available to new skin substitutes that meet the pass-through criteria. The skin substitute products that would be unconditionally packaged under this proposal and assigned to status indicator ''N'' for CY 2014 are listed in Addendum P of this CY 2014 OPPS/ASC proposed rule. The proposed payment for CPT codes 15271 through 15278, including the cost of the packaged skin substitutes, for CY 2014 are listed in Addendum B of this proposed rule. These addenda are available on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

(3) Clinical Diagnostic Laboratory Tests

Since the beginning of the OPPS, clinical diagnostic laboratory tests (laboratory tests) provided in the hospital outpatient setting have been separately paid to hospitals at Clinical Laboratory Fee Schedule (CLFS) rates (65 FR 18442). Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. Under this authority, the Secretary excluded from the OPPS those services that are paid under fee schedules or other payment systems. As stated in the April 17, 2000 OPPS final rule with comment period: ''Rather than duplicate existing payment systems that are effectively achieving consistency of payments across different service delivery sites, we proposed to exclude from the outpatient PPS those services furnished in a hospital outpatient setting that were already subject to an existing fee schedule or other prospectively determined payment rate'' (65 FR 18442). Because payment rates for laboratory tests were based on the CLFS, laboratory tests are among the services excluded from the OPPS. We codified this policy at 42 CFR 419.22(l).

As discussed above, it is our intent to make the OPPS a more complete prospective payment system, and less of a fee schedule-type payment system that makes separate payment for each separately coded item. We have examined the services performed in the hospital outpatient setting to determine those services that we believe should be packaged in order to make the OPPS a more complete and robust prospective payment system. We were guided by our longstanding OPPS packaging principle of packaging the payment of items or services when they are provided along with primary services they support. Based on this approach, we believe that laboratory tests (other than molecular pathology tests, as discussed below) that are integral, ancillary, supportive, dependent, or adjunctive to the primary services provided in the hospital outpatient setting are services that should be packaged. Laboratory tests and their results support clinical decisionmaking for a broad spectrum of primary services provided in the hospital outpatient setting, including surgery and diagnostic evaluations. Therefore, except as discussed below for molecular pathology tests, we are proposing to package laboratory tests when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting. We are proposing that laboratory tests would be integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting when they are provided on the same date of service as the primary service and when they are ordered by the same practitioner who ordered the primary service. We would consider a laboratory test to be unrelated to a primary service and, thus, not part of this packaging policy when the laboratory test is the only service provided on that date of service or when the laboratory test is provided on the

same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service provided in the hospital outpatient setting. The laboratory tests not included in the packaging proposal would continue to be paid separately at CLFS rates when billed on a 14X bill type.

We are proposing an exception for molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 from this proposed packaging policy. We are not proposing that these services be packaged because we believe that these relatively new tests have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we are proposing to package. As we gain more experience with these molecular pathology tests, we will consider if packaging in the OPPS would be appropriate for these types of tests.

In addition to the laboratory packaging policy proposals described above, we considered proposing an alternative laboratory packaging policy that would package those laboratory tests meeting the proposed policies above, but also include a dollar threshold policy similar to the approach we use for separately paid drugs and biologicals in the OPPS so that only laboratory tests (meeting the proposed standards above) with CLFS payment rates below a certain dollar threshold amount would be packaged. Under this alternative policy, tests meeting the proposed standards above, but for which the CLFS payment rates are above the threshold amount, would continue to be separately paid. We decided not to propose this alternative policy because, as discussed above in the background section, our packaging policies generally do not consider the cost of the individual items and services that are packaged, meaning that we package both inexpensive and expensive items according to OPPS packaging principles.

We recognize that the Medicare Part B deductible and coinsurance generally do not apply for laboratory tests paid to hospitals at CLFS rates, but that the deductible and coinsurance would apply to laboratory tests packaged into other services in the OPPS. The purpose of the laboratory packaging proposal is not to shift program costs onto beneficiaries, but to encourage greater efficiency by hospitals and the most economical delivery of medically necessary laboratory tests. We estimate that the combination of packaging laboratory tests into a wide array of primary services provided in the hospital outpatient setting combined with our long-standing methodology to adjust the copayment percentages to 20 percent as provided in section 1833(t)(3)(B)(ii) of the Act and as discussed in section II.I. of this proposed rule, and the limitation on the copayment amount for a procedure to the inpatient hospital deductible as set forth at section 1833(t)(8)(C)(i) of the Act would fully offset the financial impact on Medicare beneficiaries receiving laboratory tests that would be subject to the proposed packaging policy. Further, we believe that creating these larger bundles will result in a more efficient use of laboratory services when they are adjunctive to an outpatient service. In addition, to the extent that the coinsurance and deductible do not apply under the CLFS, they would continue not to apply for tests that are ordered, provided, and billed independently from a primary service as discussed above, or for molecular pathology tests. We are inviting public comments on the effect of packaging laboratory tests on beneficiary coinsurance.

The laboratory test codes that we are proposing to be packaged and assigned status indicator ''N'' for CY 2014 are listed in Addendum P of this proposed rule (which is available via the Internet on the CMS Web site. We are proposing to revise the regulation text at § 419.2(b) and § 419.22(l) to reflect this laboratory test packaging proposal.

(4) Procedures Described By Add-On Codes

Add-on codes describe procedures that are always performed in addition to a primary procedure. Add-on codes can be either CPT codes or Level II HCPCS codes. For example, the procedure described by CPT code 11001 is ''Debridement of extensive eczematous or infected skin; each additional 10% of the body surface, or part thereof (list separately in addition to code for primary procedure).'' This code is used for additional debridement beyond that described by the primary procedure code. Currently, add-on codes are treated like other codes in the OPPS. Add-on codes typically received separate payment based on an APC assignment, and are typically assigned status indicator ''T.''

Procedures described by add-on codes represent an extension or continuation of a primary procedure, which means that they are typically supportive, dependent, or adjunctive to a primary surgical procedure. The parent code defines the purpose of the patient encounter and the add-on code typically describes additional incremental work, when the extent of the procedure encompasses a range rather than a single defined endpoint applicable to all patients. For example, add-on CPT code 11001 is used for each additional 10 percent of debridement. Therefore, according to longstanding OPPS packaging principles described above and the dependent nature and adjunctive characteristics of procedures described by add-on codes, we believe that such procedures should be packaged with the primary procedure. For CY 2014, we are proposing to unconditionally package all procedures described by add-on codes in the OPPS.

There is an additional benefit to packaging add-on codes—more accurate OPPS payment for procedures described by add-on codes. Currently, calculating mean costs for procedures described by add-on codes is problematic in the OPPS because we cannot determine which costs on a claim are attributable to the primary procedure and which costs are attributable to the add-on procedure. Furthermore, because we use single claims and ''pseudo'' single procedure claims for ratesetting, we generally must rely on incorrectly coded claims containing only the add-on code to calculate payment rates for add-on procedures. Claims containing only an add-on code are incorrectly coded because they should be reported with (or ''added-on'') a primary procedure. Packaging the line item costs associated with an add-on code into the cost of the primary procedure will help address this ratesetting concern because the costs of the add-on code would be packaged into the primary procedure, and we would no longer have to calculate costs for add-on codes based on miscoded claims. In addition, packaging add-on codes would increase the number of single bills available for ratesetting for the primary procedures.

We are revising the regulations at § 419.2(b) to include the packaging of add-on codes. The specific add-on codes that we are proposing to be unconditionally packaged and assigned status indicator ''N'' for CY 2014 are listed in Addendum P of this proposed rule, which is available via the Internet on the CMS Web site.

(5) Ancillary Services (Status Indicator ''X'')

Under the OPPS, we currently pay separately for certain ancillary services that are assigned to status indicator ''X,'' defined as ''ancillary services.'' Some

other services that are ancillary to other services are currently packaged in the OPPS. Those ancillary services assigned status indicator ''X'' in the OPPS and paid separately are, by definition, ancillary relative to primary services provided in the OPPS and include many minor diagnostic tests that are typically performed with a primary service, although there are instances where such services are not always performed with a primary service and may be performed alone.

As mentioned above, our intent is that the OPPS be more of a prospective payment system through expanding packaging. Given that the longstanding OPPS policy is to package items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service, we believe that these ancillary services, which are assigned status indicator ''X,'' should be packaged when they are performed with another service, but should continue to be separately paid when performed alone. This packaging approach is most consistent with a prospective payment system and the regulations at § 419.2(b) that packages ancillary services into primary services while preserving separate payment for those instances in which one of these services is provided alone (not with a separate primary service) to a hospital outpatient.

In summary, we are proposing to conditionally package all ancillary services that were previously assigned a status indicator of ''X'' and assign these services to status indicator ''Q1'' (packaged when provided with a service assigned a status indicator of ''S,'' ''T,'' or ''V''). Status indicator ''X'' would be discontinued. To encourage maximum flexibility to beneficiaries across different sites of service, we are not proposing to conditionally package preventive services assigned to status indicator ''X'' and instead are proposing to change the status indicator for preventive services from the currently assigned status indicator ''X'' to status indicator ''S.'' The specific codes for procedures assigned to status indicator ''X'' that are proposed to be conditionally packaged and assigned to status indicator ''Q1'' for CY 2014 are listed in Addendum P of this proposed rule, which is available via the Internet on the CMS Web site.

(6) Diagnostic Tests on the Bypass List

For the CY 2013 OPPS, we implemented a bypass list to convert lines from multiple procedure claims into ''pseudo'' single procedure claims. We are proposing to continue developing ''pseudo'' single procedure claims using a bypass list for the CY 2014 OPPS, as discussed in section II.A.1.b. of this proposed rule. The bypass list of separately paid services is used to convert claims with multiple separately payable procedures, which are generally not used for ratesetting purposes, into claims with a single separately paid procedure that can be used for ratesetting. Services on the bypass list have limited associated packaged costs so they can be bypassed when assigning packaged costs on a claim to a separately paid procedure on the same claim.

As noted above, beginning in CY 2008, we packaged several diagnostic items and services including guidance services, image processing services, intraoperative services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals, and contrast agents. In this proposed rule, we also are proposing to conditionally package several diagnostic items and services, including drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, ancillary services (many of which are diagnostic tests), and laboratory tests. We believe that the diagnostic tests on the bypass list share many of the characteristics with these other conditionally or unconditionally packaged or proposed packaged categories of items and services in that they are diagnostic and are integral, ancillary, supportive, dependent, or adjunctive to a primary service. Examples include a barium swallow test (CPT code 74220) and a visual field examination (CPT code 92081). Given the nature of these services, we are proposing to conditionally package these procedures. We recognize that some of these services are sometimes provided without other services and, therefore, they will continue to be separately paid in those circumstances.

We are proposing that these codes be assigned status indicator ''Q1'' beginning in the CY 2014 OPPS. Some of these diagnostic tests on the bypass list are currently assigned to status indicator ''X'' and, therefore, would be conditionally packaged under the proposed policy to conditionally package ancillary services currently assigned status indicator ''X.'' The only diagnostic codes on the bypass list affected by this proposal are currently assigned to status indicator ''S.'' The specific codes for the diagnostic tests on the bypass list that we are proposing to be conditionally packaged and assigned to status indicator ''Q1'' for CY 2014 are listed in Addendum P of this proposed rule, which is available via the Internet on the CMS Web site. Similar to our conditional packaging proposal for services previously assigned to status indicator ''X,'' we are not proposing to conditionally package preventive services that are diagnostic tests on the bypass list.

(7) Device Removal Procedures

Implantable devices frequently require removal or replacement due to wear, failure, recall, and infection, among others. Since the beginning of the OPPS, implantable devices have been packaged (either as supplies, implantable prosthetics, or implantable DME) into their associated procedures. Device removal is sometimes described by a code that may include repair or replacement. In other cases, device removal is described by a separate code that only describes removal of a device. Device removal procedures are frequently performed with procedures to repair or replace devices, although it is possible that device removal may occur without repair or replacement if the clinical indication for the device that was removed no longer exists. When a separately coded device removal procedure is performed with a separately coded device repair or replacement procedure, the device removal procedure actually represents a part of an overall procedure that is removal with repair or replacement of the device.

Given that a separately coded device removal that accompanies a device repair or replacement procedure represents a service that is integral and supportive to a primary service, we are proposing to conditionally package device removal codes when they are billed with other surgical procedures involving repair or replacement. We believe that this conditional packaging policy is appropriate under longstanding OPPS packaging principles because these device removal procedures are an integral and supportive step in a more comprehensive overall procedure. Furthermore, conditionally packaging these device removal procedures with the replacement or revision codes would be consistent with our packaging policies for other dependent services. The specific codes for the device removal procedures that we are proposing to be conditionally packaged and assigned to status indicator ''Q2'' for CY 2014 are listed in Addendum P of this proposed rule, which is available via the Internet on the CMS Web site.

d. Impact of the New Packaging Proposals

We have examined the proposed aggregate impact of making these proposed changes to packaging for CY

2014. Because the OPPS is a budget neutral payment system in which the amount of the relative payment weight in the system is annually adjusted for changes in expenditures created by changes in APC weights and codes (but is not currently adjusted based on estimated growth in service volume), the effects of the packaging changes that we are proposing would result in changes to scaled weights and, therefore, to the payment rates for all separately paid procedures. These proposed changes would result from shifts in mean costs as a result of increased packaging, changes in multiple procedure discounting patterns, and a higher weight scaler that is applied to all unscaled APC weights. Further, to properly budget neutralize the money that would previously have been paid through other payment systems, we have included those payments when performing OPPS budget neutrality calculations. We refer readers to section II.A.4. of this proposed rule for an explanation of the weight scaler for OPPS budget neutrality. In a budget neutral system, the monies previously paid for services that are now proposed to be packaged are not lost, but are redistributed to all other services. A higher weight scaler would increase payment rates relative to observed mean costs for independent services by redistributing the lost weight of packaged items that historically have been paid separately and the lost weight when the mean costs of independent services do not completely reflect the full incremental cost of the packaged services. The impact of this proposed change on proposed CY 2014 OPPS payments is discussed in section XXIII.A. of this proposed rule, and the impact on various classifications of hospitals is shown in Column 5 in Table 39 in that section.

We estimate that our CY 2014 packaging proposal would redistribute approximately 4 percent of the estimated CY 2013 base year expenditures under the OPPS. If the relative payment weight for a particular APC decreases as a result of the proposed packaging approach, the increased weight scaler may or may not result in a relative payment weight that is equal to or greater than the relative weight that would occur without the proposed packaging approach. In general, the packaging policies that we are proposing would have more effect on payment for some services than on payment for others because the dependent items and services that we are proposing for packaging are furnished more often with some independent services than with others. However, because of the amount of relative payment weight that would be redistributed by this proposal, there would be some impact on payments for all OPPS services whose rates are set based on relative payment weights, and the impact on any given hospital would vary based on the mix of services furnished by the hospital.

e. Clarification Regarding Supplies That Are Packaged in the OPPS

Under the regulations at § 419.2(b)(4), medical and surgical supplies and equipment are packaged in the OPPS. Supplies is a large category of items that typically are either for single patient use or have a shorter life span in use than equipment. Packaged supplies can include certain drugs, biologicals, and radiopharmaceuticals. The only supplies that are sometimes paid separately in the OPPS are prosthetic supplies under § 419.22(j), and if paid separately, they are paid according to the DMEPOS fee schedule. All other supplies are unconditionally packaged in the OPPS.

In our annual review of the OPPS for CY 2014, we discovered many supplies that should be packaged in the OPPS according to § 419.2(b)(4), but that are currently assigned to status indicator ''A'' and are separately paid in the hospital outpatient setting according to the DMEPOS fee schedule. For CY 2014, we are proposing to revise the status indicator for all supplies described by Level II HCPCS A-codes (except for prosthetic supplies) from status indicator ''A'' to ''N,'' so that these supplies would be unconditionally packaged as required by § 419.2(b)(4). The specific Level II HCPCS A-codes whose status indicator will be revised from ''A'' to ''N'' are listed in Addendum P of this CY 2014 OPPS/ASC proposed rule, which is available via the Internet on the CMS Web site.

f. Proposed Revision and Clarification of the Regulations at 42 CFR 419.2(b) and 42 CFR 419.22

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68272), after consideration of public comments we received on the proposed rule, we clarified the regulatory language at § 419.2(b) to make explicit that the OPPS payments for the included costs of the nonexclusive list of items and services covered under the OPPS referred to in this paragraph are packaged into the payments for the related procedures or services with which such items and services are provided. In this proposed rule, we are proposing to further revise this regulation to add the packaging categories that were adopted in CYs 2008 and 2009 in addition to the new proposed policies described above. We also are proposing to make some further minor revisions and editorial clarifications to the existing language of § 419.2(b) to make it more clearly reflect current packaging policy. Finally, we are proposing to revise the list of services excluded from the OPPS at § 419.22.

g. Comment Solicitation on Increased Packaging for Imaging Services

We currently package several kinds of imaging services in the OPPS, including image guidance services, image processing services, intraoperative imaging, and imaging supervision and interpretation services. In addition, some imaging services are included in this year's proposal to conditionally package ancillary services and diagnostic tests on the bypass list. In addition to these imaging services that are either packaged or proposed to be packaged, we are contemplating a proposal for CY 2015 that would conditionally package all imaging services with any associated surgical procedures. Imaging services not provided with a surgical procedure would continue to either be separately paid according to a standard clinical APC or a composite APC. We are requesting public comments on this potential CY 2015 proposal.

h. Summary of CY 2014 Packaging Proposals

Beginning in CY 2014, we are proposing to unconditionally package or conditionally package the following items and services and to add them to the list of OPPS packaged items and services in § 419.2(b):

(1) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure;

(2) Drugs and biologicals that function as supplies or devices when used in a surgical procedure;

(3) Clinical diagnostic laboratory tests;

(4) Procedures described by add-on codes;

(5) Ancillary services (status indicator ''X'');

(6) Diagnostic tests on the bypass list; and

(7) Device removal procedures.

We believe that each of the above proposed unconditionally or conditionally packaged categories of items or services is appropriate according to existing packaging policies or expansions of existing packaging policies. However, we recognize that

decisions about packaging payment involve a balance between ensuring that payment is adequate to enable the hospital to provide quality care while establishing incentives for efficiency through larger units of payment. Therefore, we are inviting public comments regarding our packaging proposals for the CY 2014 OPPS.

The HCPCS codes that we are proposing to be packaged either unconditionally (for which we are proposing to assign status indicator ''N''), or conditionally (for which we are proposing to assign status indicator ''Q1'' or ''Q2''), for CY 2014 are displayed in both Addendum P and Addendum B of this proposed rule. The supporting documents for this proposed rule, including but not limited to the Addenda, are available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

4. Proposed Calculation of OPPS Scaled Payment Weights

For CY 2014, we are proposing to calculate the relative payment weights for each APC for CY 2014 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) using the APC costs discussed in sections II.A.1. and II.A.2. of this proposed rule. In years prior to CY 2007, we standardized all the relative payment weights to APC 0601 (Mid-Level Clinic Visit) because mid-level clinic visits were among the most frequently performed services in the hospital outpatient setting. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601 to derive the relative payment weight for each APC.

Beginning with the CY 2007 OPPS (71 FR 67990), we standardized all of the relative payment weights for APC 0606 (Level 3 Clinic Visits) because we deleted APC 0601 as part of the reconfiguration of the clinic visit APCs. We selected APC 0606 as the base because APC 0606 was the mid-level clinic visit APC (that is, Level 3 of five levels).

For the CY 2013 OPPS (77 FR 68283), we established a policy of using geometric mean-based APC costs to calculate relative payment weights. For the CY 2014 OPPS, we are proposing to continue basing the relative payment weights on which OPPS payments will be made by using geometric mean costs. As we discuss in section VII. of this proposed rule, we are proposing to reconfigure the CY 2014 visit APCs so that they would include a single level for each visit type. However, in an effort to maintain consistency in calculating unscaled weights that represent the cost of some of the most frequently provided services, we are proposing to use the cost of the clinic visit APC in calculating unscaled weights, which for CY 2014 is proposed APC 0634. While we have previously used APC 0606 as the base from which to develop the OPPS budget neutral weight scaler, under our proposal to reconfigure the visit APCs, we would have a single APC for each visit type. The proposal to reconfigure the visit APCs is discussed in more detail in section VII. of this proposed rule. Following our general methodology for establishing relative payment weights derived from APC costs, but using the proposed CY 2014 geometric mean cost for APC 0634, for CY 2014, we are proposing to assign APC 0634 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for APC 0634 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to base the proposed relative payment weights for all other APCs does not affect the payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2014 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we are proposing to compare the estimated aggregate weight using the CY 2013 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2014 unscaled relative payment weights.

For CY 2013, we multiplied the CY 2013 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2012 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2014, we are proposing the same process using the proposed CY 2014 unscaled relative payment weights rather than scaled relative payment weights. We are proposing to calculate the weight scaler by dividing the CY 2013 estimated aggregate weight by the proposed CY 2014 estimated aggregate weight. The service-mix is the same in the current and prospective years because we use the same set of claims for service volume in calculating the aggregate weight for each year. We note that, as a result of the CY 2014 proposed OPPS packaging policy for laboratory tests described in section II.A.3.b.(3) of this proposed rule, we would need to incorporate the estimated relative payment weights from those services. Therefore, the CY 2013 estimated OPPS aggregate weight would include payments for outpatient laboratory tests paid at the CLFS rates.

For a detailed discussion of the weight scaler calculation, we refer readers to the OPPS claims accounting document available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

We are proposing to include estimated payments to CMHCs in our comparison of the estimated unscaled relative payment weights in CY 2014 to the estimated total relative payment weights in CY 2013 using CY 2012 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we adjusted the proposed CY 2014 unscaled relative payment weights for purposes of budget neutrality. The proposed CY 2014 unscaled relative payment weights were adjusted by multiplying them by a proposed weight scaler of 1.2143 to ensure that the proposed CY 2014 relative payment weights are budget neutral.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act states that ''Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.'' Therefore, the cost of those SCODs (as discussed in section V.B.3. of this proposed rule) is included in the proposed budget neutrality calculations for the CY 2014 OPPS.

The proposed CY 2014 unscaled relative payment weights listed in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) incorporate the proposed recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27572), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2013 forecast of the FY 2014 market basket increase, the proposed FY 2014 IPPS market basket update is 2.5 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(iii) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2014.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27572), we discussed the calculation of the proposed MFP adjustment for FY 2014, which is 0.4 percentage point.

We are proposing that if more recent data become subsequently available after the publication of this proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the CY 2014 market basket update and the MFP adjustment, components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2014 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2014, section 1833(t)(3)(G)(iii) of the Act provides a 0.3 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(iii) of the Act, we are proposing to apply a 0.3 percentage point reduction to the OPD fee schedule increase factor for CY 2014.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 for a year, and may result in payment rates under the OPPS for a year being less than such payment rates for the preceding year. As described in further detail below, we are proposing to apply an OPD fee schedule increase factor of 1.8 percent for the CY 2014 OPPS (which is 2.5 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.4 percentage point MFP adjustment, and less the 0.3 percentage point additional adjustment).

We note that hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. As a result, those hospitals failing to meet the Hospital OQR Program reporting requirements would receive an OPD fee schedule increase factor of −0.2 percent (which is 2.5 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.4 percentage point MFP adjustment, less the 0.3 percentage point additional adjustment, and less 2.0 percentage points for the Hospital OQR Program reduction). For further discussion of the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

In this proposed rule, we are proposing to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (*5*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2014, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(iii) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.3 percentage point for CY 2014.

To set the OPPS conversion factor for CY 2014, we are proposing to increase the CY 2013 conversion factor of $71.313 by 1.8 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing to further adjust the conversion factor for CY 2014 to ensure that any revisions made to the updates for a revised wage index and rural adjustment are made on a budget neutral basis. We are proposing to calculate an overall proposed budget neutrality factor of 1.004 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2014 IPPS wage indices to those payments using the current (FY 2013) IPPS wage indices, as adopted on a calendar year basis for the OPPS.

For CY 2014, we are not proposing to make a change to our rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

For CY 2014, we are proposing to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule. We are proposing to calculate a CY 2014 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing the estimated total CY 2014 payments under section 1833(t) of the Act, including the proposed CY 2014 cancer hospital payment adjustment, to the estimated CY 2014 total payments using the CY 2013 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The difference in the CY 2014 estimated payments as a result of applying the proposed CY 2014 cancer hospital payment adjustment relative to the CY 2013 final cancer hospital payment adjustment has a limited impact on the budget neutrality calculation. Therefore, we are proposing to apply a proposed budget neutrality adjustment factor of 1.0001 to the conversion factor to ensure that the cancer hospital payment adjustment is budget neutral.

For this proposed rule, we estimate that pass-through spending for both drugs and biologicals and devices for CY 2014 would equal approximately $12 million, which represents 0.02

percent of total projected CY 2014 OPPS spending. Therefore, the proposed conversion factor also would be adjusted by the difference between the 0.15 percent estimate of pass-through spending for CY 2013 and the 0.02 percent estimate of CY 2014 pass-through spending, resulting in a proposed adjustment for CY 2014 of 0.13 percent. Finally, estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2014.

The proposed OPD fee schedule increase factor of 1.8 percent for CY 2014 (that is, the estimate of the hospital inpatient market basket percentage increase of 2.5 percent less the proposed 0.4 percentage point MFP adjustment and less the 0.3 percentage point required under section 1833(t)(3)(F) of the Act), the required proposed wage index budget neutrality adjustment of approximately 1.0004, the proposed cancer hospital payment adjustment of 1.0001, and the proposed adjustment of 0.13 percent of projected OPPS spending for the difference in the pass-through spending result in a proposed conversion factor for CY 2014 of $72.728.

Hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates made for their services as required by section 1833(t)(17) of the Act. For a complete discussion of the Hospital OQR Program requirements and the payment reduction for hospitals that fail to meet those requirements, we refer readers to section XIII.G. of this proposed rule. To calculate the proposed CY 2014 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the Hospital OQR Program for the full CY 2014 payment update, we are proposing to make all other adjustments discussed above, but using a proposed reduced OPD fee schedule update factor of −0.2 percent (that is, the proposed OPD fee schedule increase factor of 1.8 percent further reduced by 2.0 percentage points as required by section 1833(t)(17)(A)(i) of the Act for failure to comply with the Hospital OQR requirements). This results in a proposed reduced conversion factor for CY 2014 of $71.273 for those hospitals that fail to meet the Hospital OQR requirements (a difference of −$1.455 in the conversion factor relative to those hospitals that met the Hospital OQR requirements).

In summary, for CY 2014, we are proposing to use a conversion factor of $72.728 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. We are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*5*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2014 in order to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(iii) of the Act. We also are proposing to use a reduced conversion factor of $71.273 in the calculation of payments for hospitals that fail to comply with the Hospital OQR Program requirements to reflect the reduction to the OPD fee schedule increase factor that is required by section 1833(t)(17) of the Act.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to ''determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner'' (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). Therefore, we are not proposing to revise this policy for the CY 2014 OPPS. We refer readers to section II.H. of this proposed rule for a description and example of how the wage index for a particular hospital is used to determine the payment for the hospital. As discussed in section II.A.2.c. of this proposed rule, for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed FY 2014 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and the copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the original OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Thus, the wage index that applies to a particular acute care short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believed that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). As discussed in that final rule with comment period, section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines ''frontier State,'' and amended section 1833(t) of the Act to add new paragraph (19), which requires a ''frontier State'' wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements in § 419.43(c)(2) and (c)(3) of our regulations. For the CY 2014 OPPS, we will implement this provision in the same manner as we did since CY 2011. That is, frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, rural and imputed floor, and rural floor budget neutrality) is less than 1.00. Similar to our current policy for HOPDs that are affiliated with multicampus hospital systems, the HOPD would receive a wage index based on the geographic location of the specific inpatient hospital with which it is associated. Therefore, if the associated hospital is located in a frontier State, the wage index adjustment applicable for the hospital would also apply for the affiliated HOPD. We refer readers to the FY 2011, FY 2012, and FY 2013 IPPS/LTCH PPS final rules (75 FR 50160 through 50161, 76 FR 51793, 51795, and 51825, and 77 FR 53369 through 53370, respectively) and the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27556 through 27557) for discussions

regarding this provision, including our methodology for identifying which areas meet the definition of frontier States as provided for in section 1886(d)(3)(E)(iii)(II) of the Act.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2014 IPPS wage indices continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural and imputed floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552 through 27561) for a detailed discussion of all proposed changes to the FY 2014 IPPS wage indices. In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

For purposes of the OPPS, we are proposing to continue our policy for CY 2014 of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173)). We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment. Table 4J listed in the FY 2014 IPPS/LTCH PPS proposed rule (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment and hospitals that would receive the adjustment for FY 2014. We also note that, beginning with FY 2012, under the IPPS, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the disproportionate share hospital (DSH) payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53371) for a more detailed discussion on the Lugar redesignation waiver for the out-migration adjustment. As we have done in prior years, we are including Table 4J from the FY 2014 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2014 OPPS. Addendum L is available via the Internet on the CMS Web site.

As discussed in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552 through 27553), the Office of Management and Budget (OMB) issued revisions to the current geographic area designations on February 28, 2013, that included a number of significant changes such as new CBSAs, urban counties that become rural, rural counties that become urban, and splitting existing CBSAs (OMB Bulletin 13–01. This bulletin can be found at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. All of these designations have corresponding effects on the wage index system and its adjustments. In order to allow for sufficient time to assess the new revisions and their ramifications, we intend to propose changes to the IPPS wage index based on the newest CBSA designations in the FY 2015 IPPS/LTCH PPS proposed rule. Similarly, in the OPPS, which uses the IPPS wage index, we intend to propose changes based on the new OMB revisions in the CY 2015 OPPS/ASC proposed rule, consistent with any proposals in the FY 2015 IPPS/LTCH PPS proposed rule.

As stated earlier in this section, we continue to believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. Therefore, we are not proposing to change our current regulations which require that we use the FY 2014 IPPS wage indices for calculating OPPS payments in CY 2014. With the exception of the proposed out-migration wage adjustment table (Addendum L to this proposed rule, which is available via the Internet on the CMS Web site), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the proposed FY 2014 IPPS wage indices referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At this link, readers will find a link to the proposed FY 2014 IPPS wage index tables.

D. Proposed Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. Medicare contractors cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned above until a hospital's Medicare contractor is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, hospitals that are new, have not accepted assignment of an existing hospital's provider agreement, and have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11). In this proposed rule, we are proposing to update the default ratios for CY 2014 using the most recent cost report data. We discuss our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009.

For CY 2014, we are proposing to continue to use our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we use to adjust charges to costs on claims data for setting the proposed CY 2014 OPPS relative payment weights. Table 9 below lists the proposed CY 2014 default urban and rural CCRs by State and compares them to last year's default CCRs. These proposed CCRs represent the ratio of total costs to total charges for those cost centers relevant to outpatient services from each hospital's most recently submitted cost report, weighted by Medicare Part B charges. We also are proposing to adjust ratios from submitted cost reports to reflect the final settled status by applying the differential between settled to submitted overall CCRs for the cost centers relevant to outpatient services from the most recent pair of final settled and submitted cost reports. We then are

proposing to weight each hospital's CCR by the volume of separately paid line-items on hospital claims corresponding to the year of the majority of cost reports used to calculate the overall CCRs. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66680 through 66682) and prior OPPS rules for a more detailed discussion of our established methodology for calculating the statewide average default CCRs, including the hospitals used in our calculations and our trimming criteria.

For Maryland, we used an overall weighted average CCR for all hospitals in the Nation as a substitute for Maryland CCRs. Few hospitals in Maryland are eligible to receive payment under the OPPS, which limits the data available to calculate an accurate and representative CCR. The weighted CCR is used for Maryland because it takes into account each hospital's volume, rather than treating each hospital equally. We refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65822) for further discussion and the rationale for our longstanding policy of using the national average CCR for Maryland. In general, observed changes in the statewide average default CCRs between CY 2013 and CY 2014 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 9 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2014.

TABLE 9—PROPOSED CY 2014 STATEWIDE AVERAGE CCRS

State	Urban/rural	Proposed CY 2014 default CCR	Previous default CCR (CY 2013 OPPS final rule)
ALASKA	RURAL	0.472	0.489
ALASKA	URBAN	0.296	0.307
ALABAMA	RURAL	0.223	0.209
ALABAMA	URBAN	0.198	0.193
ARKANSAS	RURAL	0.227	0.219
ARKANSAS	URBAN	0.230	0.234
ARIZONA	RURAL	0.223	0.238
ARIZONA	URBAN	0.188	0.190
CALIFORNIA	RURAL	0.210	0.192
CALIFORNIA	URBAN	0.210	0.202
COLORADO	RURAL	0.396	0.331
COLORADO	URBAN	0.222	0.226
CONNECTICUT	RURAL	0.359	0.364
CONNECTICUT	URBAN	0.285	0.287
DISTRICT OF COLUMBIA	URBAN	0.282	0.302
DELAWARE	RURAL	0.278	0.282
DELAWARE	URBAN	0.331	0.353
FLORIDA	RURAL	0.172	0.182
FLORIDA	URBAN	0.166	0.167
GEORGIA	RURAL	0.271	0.237
GEORGIA	URBAN	0.209	0.214
HAWAII	RURAL	0.350	0.323
HAWAII	URBAN	0.311	0.306
IOWA	RURAL	0.312	0.296
IOWA	URBAN	0.284	0.269
IDAHO	RURAL	0.333	0.417
IDAHO	URBAN	0.491	0.357
ILLINOIS	RURAL	0.258	0.240
ILLINOIS	URBAN	0.235	0.230
INDIANA	RURAL	0.358	0.285
INDIANA	URBAN	0.288	0.256
KANSAS	RURAL	0.298	0.290
KANSAS	URBAN	0.245	0.210
KENTUCKY	RURAL	0.226	0.217
KENTUCKY	URBAN	0.232	0.241
LOUISIANA	RURAL	0.258	0.242
LOUISIANA	URBAN	0.229	0.225
MASSACHUSETTS	RURAL	0.436	0.427
MASSACHUSETTS	URBAN	0.330	0.323
MAINE	RURAL	0.443	0.445
MAINE	URBAN	0.455	0.449
MARYLAND	RURAL	0.286	0.275
MARYLAND	URBAN	0.251	0.246
MICHIGAN	RURAL	0.353	0.303
MICHIGAN	URBAN	0.316	0.303
MINNESOTA	RURAL	0.462	0.469
MINNESOTA	URBAN	0.339	0.321
MISSOURI	RURAL	0.282	0.241
MISSOURI	URBAN	0.287	0.262
MISSISSIPPI	RURAL	0.228	0.226
MISSISSIPPI	URBAN	0.187	0.182
MONTANA	RURAL	0.486	0.431

TABLE 9—PROPOSED CY 2014 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	Proposed CY 2014 default CCR	Previous default CCR (CY 2013 OPPS final rule)
MONTANA	URBAN	0.407	0.384
NORTH CAROLINA	RURAL	0.251	0.253
NORTH CAROLINA	URBAN	0.255	0.254
NORTH DAKOTA	RURAL	0.667	0.322
NORTH DAKOTA	URBAN	0.376	0.414
NEBRASKA	RURAL	0.333	0.318
NEBRASKA	URBAN	0.251	0.254
NEW HAMPSHIRE	RURAL	0.325	0.317
NEW HAMPSHIRE	URBAN	0.300	0.292
NEW JERSEY	URBAN	0.212	0.207
NEW MEXICO	RURAL	0.294	0.256
NEW MEXICO	URBAN	0.307	0.279
NEVADA	RURAL	0.234	0.234
NEVADA	URBAN	0.159	0.162
NEW YORK	RURAL	0.347	0.420
NEW YORK	URBAN	0.347	0.369
OHIO	RURAL	0.337	0.321
OHIO	URBAN	0.237	0.237
OKLAHOMA	RURAL	0.253	0.239
OKLAHOMA	URBAN	0.210	0.212
OREGON	RURAL	0.332	0.314
OREGON	URBAN	0.352	0.335
PENNSYLVANIA	RURAL	0.270	0.267
PENNSYLVANIA	URBAN	0.199	0.200
PUERTO RICO	URBAN	0.600	0.504
RHODE ISLAND	URBAN	0.310	0.264
SOUTH CAROLINA	RURAL	0.196	0.211
SOUTH CAROLINA	URBAN	0.210	0.214
SOUTH DAKOTA	RURAL	0.309	0.307
SOUTH DAKOTA	URBAN	0.208	0.218
TENNESSEE	RURAL	0.212	0.209
TENNESSEE	URBAN	0.200	0.195
TEXAS	RURAL	0.233	0.235
TEXAS	URBAN	0.203	0.206
UTAH	RURAL	0.343	0.374
UTAH	URBAN	0.338	0.359
VIRGINIA	RURAL	0.223	0.227
VIRGINIA	URBAN	0.243	0.237
VERMONT	RURAL	0.429	0.408
VERMONT	URBAN	0.395	0.384
WASHINGTON	RURAL	0.315	0.366
WASHINGTON	URBAN	0.322	0.301
WISCONSIN	RURAL	0.347	0.345
WISCONSIN	URBAN	0.308	0.307
WEST VIRGINIA	RURAL	0.294	0.277
WEST VIRGINIA	URBAN	0.327	0.338
WYOMING	RURAL	0.444	0.379
WYOMING	URBAN	0.279	0.301
ALASKA	RURAL	0.472	0.489
ALASKA	URBAN	0.296	0.307

E. Proposed Adjustment for Rural SCHs and EACHs Under Section 1833(t)(13)(B) of the Act

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In CY 2007, we became aware that we did not specifically address whether the adjustment applies to EACHs, which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Thus, under the statute, EACHs are treated as SCHs. Therefore, in the CY 2007 OPPS/

ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) of the regulations to clarify that EACHs also are eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, three hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2013. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2014 OPPS, we are proposing to continue our policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Proposed OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. There are 11 cancer hospitals that meet the classification criteria in section 1886(d)(1)(B)(v) of the Act that are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), Congress established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to hold harmless cancer hospitals and children's hospitals based on their pre-BBA amount under the OPPS. As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPS) or hold harmless payments to ensure that they do not receive a payment that is lower under the OPPS than the payment they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is an amount equal to the product of the reasonable cost of the hospital for covered outpatient services for the portions of the hospital's cost reporting period (or periods) occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount,'' including the determination of the base PCR, are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital and Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, as applicable) each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act of 2010 amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed the costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. In addition, section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by such hospitals when studying cancer hospital costliness. Further, section 1833(t)(18)(B) of the Act provides that if the Secretary determines that costs by these cancer hospitals with respect to APC groups are determined to be greater than the costs of other hospitals furnishing services under section 1833(t) of the Act, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. After conducting the study required by section 1833(t)(18)(A) of the Act, we determined in 2011 that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on our findings that costs incurred by cancer hospitals were greater than the costs incurred by other OPPS hospitals, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects the higher outpatient costs as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to each of the 11 cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recent submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91.

2. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2014

For CY 2014, we are proposing to continue our policy to provide additional payments to cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals using the most recent submitted or settled cost report data that are available at the time of the development of this proposed rule. To calculate the proposed CY 2014 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of this proposed rule, used to estimate costs for the CY 2014 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled. We then limited the dataset to the hospitals

with CY 2012 claims data that we used to model the impact of the proposed CY 2014 APC relative weights (3,951 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2014 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2011 to 2012. We then removed the cost report data of the 45 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 118 hospitals because the cost report data were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,788 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 90 percent of reasonable cost (a weighted average PCR of 0.90). Based on these data, we are proposing a target PCR of 0.90 to determine the CY 2014 cancer hospital payment adjustment to be paid at cost report settlement. Therefore, we are proposing that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.90 for each cancer hospital.

Table 10 below indicates the estimated percentage increase in OPPS payments to each cancer hospital for CY 2014 due to the cancer hospital payment adjustment policy. The actual amount of the CY 2014 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2014 payments and costs. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 10—ESTIMATED CY 2014 HOSPITAL–SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Estimated percentage increase in OPPS payments for CY 2014 (percent)
050146	City of Hope Helford Clinical Research Hospital	15.0
050660	USC Kenneth Norris Jr. Cancer Hospital	28.9
100079	University of Miami Hospital & Clinic	16.7
100271	H. Lee Moffitt Cancer Center & Research Institute	23.7
220162	Dana-Farber Cancer Institute	48.2
330154	Memorial Hospital for Cancer and Allied Diseases	41.4
330354	Roswell Park Cancer Institute	35.2
360242	James Cancer Hospital & Solove Research Institute	35.6
390196	Hospital of the Fox Chase Cancer Center	16.7
450076	University of Texas M. D. Anderson Cancer Center	58.9
500138	Seattle Cancer Care Alliance	55.1

G. Proposed Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS provides outlier payments on a service-by-service basis. In CY 2012, the outlier threshold was determined to be met when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,025 fixed-dollar threshold. We introduced a fixed-dollar threshold in CY 2005, in addition to the traditional multiple threshold, in order to better target outlier payments to those high-cost and complex procedures where a very costly service could present a hospital with significant financial loss. If the cost of a service meets both of these conditions, the multiple threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate. Before CY 2009, this outlier payment had historically been considered a final payment by longstanding OPPS policy. However, we implemented a reconciliation process similar to the IPPS outlier reconciliation process for cost reports with cost reporting periods beginning on or after January 1, 2009, in our CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy for the past several years to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the proposed OPPS. Our current estimate of total outlier payments as a percent of total CY 2012 OPPS payment, using available CY 2012 claims and the revised OPPS expenditure estimate for the 2013 Trustee's Report, is approximately 1.1 percent of the total aggregated OPPS payments. Therefore, for CY 2012, we estimate that we paid 0.1 percent above the CY 2012 outlier target of 1.0 percent of total aggregated OPPS payments.

As explained in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68295 through 68297), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for CY 2013. The outlier thresholds were set so that estimated CY 2013 aggregate outlier payments would equal 1.0 percent of the total estimated aggregate payments under the OPPS. Using CY 2012 claims data and CY 2013 payment rates, we currently estimate that the aggregate outlier payments for CY 2013 will be approximately 1.2 percent of the total CY 2013 OPPS payments. The difference between 1.2 percent and 1.0 percent is reflected in the regulatory impact analysis in section

XXIII. of this proposed rule. We note that we provide estimated CY 2014 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Proposed Outlier Calculation

For CY 2014, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. We are proposing that a portion of that 1.0 percent, an amount equal to 0.18 percent of outlier payments (or 0.0018 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.D. of this proposed rule, for CMHCs, we are proposing to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) or APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.D. of this proposed rule.

To ensure that the estimated CY 2014 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing that the hospital outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,775 fixed-dollar threshold.

We calculated the proposed fixed-dollar threshold using largely the standard methodology, most recently used for CY 2013 (77 FR 68295 through 68297). For purposes of estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2013 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCR, which are maintained by the Medicare contractors and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2014 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2012 claims using the same inflation factor of 1.0993 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27767). We used an inflation factor of 1.0485 to estimate CY 2013 charges from the CY 2012 charges reported on CY 2012 claims. The methodology for determining this charge inflation factor is discussed in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27767). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, for this CY 2014 OPPS/ASC proposed rule, we are proposing to apply the same CCR inflation adjustment factor that we are proposing to apply for the FY 2014 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2014 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2014, we are proposing to apply an adjustment factor of 0.9732 to the CCRs that were in the April 2013 OPSF to trend them forward from CY 2013 to CY 2014. The methodology for calculating this proposed adjustment was discussed in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27766 through 27768).

Therefore, to model hospital outlier payments for this proposed rule, we applied the overall CCRs from the April 2013 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9732 to approximate CY 2014 CCRs) to charges on CY 2012 claims that were adjusted (using the proposed charge inflation factor of 1.0993 to approximate CY 2014 charges). We simulated aggregated CY 2014 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2014 OPPS payments. We estimated that a proposed fixed-dollar threshold of $2,775, combined with the proposed multiple threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. We are proposing to continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the proposed fixed-dollar threshold of $2,775 are met. For CMHCs, we are proposing that, if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we are proposing to continue the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR Part 419, Subparts C and D. For this CY

2014 OPPS/ASC proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2014 scaled weight for the APC by the proposed CY 2014 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

We demonstrate in the steps below how to determine the APC payments that will be made in a calendar year under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V'' (as defined in Addendum D1 to this proposed rule), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements. We note that we are also proposing to create status indicator ''J1'' to reflect the proposed comprehensive APCs discussed in section II.A.2.e. of this proposed rule.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the proposed national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the proposed reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full proposed CY 2014 OPPS fee schedule increase factor of 1.8 percent.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

X = .60 * (national unadjusted payment rate)

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2014 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. (For further discussion of the proposed changes to the FY 2014 IPPS wage indices, as applied to the CY 2014 OPPS, we refer readers to section II.C. of this proposed rule.) We are proposing to continue to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this proposed rule (which is available via the Internet on the CMS Web site) contains the qualifying counties and the associated proposed wage index increase developed for the FY 2014 IPPS and listed as Table 4J in the FY 2014 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = .60 * (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted

payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

$Y = .40 * (\text{national unadjusted payment rate})$

$\text{Adjusted Medicare Payment} = Y + X_a$

Step 6. If a provider is an SCH, set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the proposed rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071

We have provided examples below of the calculation of both the proposed full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we used a provider that is located in Brooklyn, New York that is assigned to CBSA 35644. This provider bills one service that is assigned to APC 0019 (Level I Excision/Biopsy). The proposed CY 2014 full national unadjusted payment rate for APC 0019 is approximately $345.75. The proposed reduced national unadjusted payment rate for APC 0019 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $338.84. This proposed reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019. The proposed FY 2014 wage index for a provider located in CBSA 35644 in New York is 1.3158. The proposed labor-related portion of the full national unadjusted payment is approximately $272.96 (.60 * $345.75 * 1.3158). The labor-related portion of the proposed reduced national unadjusted payment is approximately $267.51 (.60 * $338.84 * 1.3158). The proposed nonlabor-related portion of the full national unadjusted payment is approximately $138.30 (.40 * $345.75). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $135.54 (.40 * $338.84). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $411.26 ($272.96 + $138.30). The sum of the reduced national adjusted payment is approximately $403.05 ($267.51 + $135.54).

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in calendar years thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. Proposed OPPS Copayment Policy

For CY 2014, we are proposing to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we are proposing to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2014, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). As discussed in section XIII.G. of this proposed rule, for CY 2014, the proposed Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that APC copayments may increase or decrease each year based on changes in the calculated APC payment rates due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS/ASC final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 0019, approximately $69.15 is 20 percent of the proposed full national unadjusted payment rate of approximately $345.75.

For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/ national unadjusted payment rate for APC

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this proposed rule. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the proposed reporting ratio of 0.980.

The proposed unadjusted copayments for services payable under the OPPS that would be effective January 1, 2014, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed full CY 2014 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

In addition, as noted above, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures and medical services;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CPT codes are established by the American Medical Association (the AMA) and Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process through OPPS quarterly update CRs. This quarterly update process offers hospitals access to codes that may more accurately describe items or services furnished and/or provides payment or more accurate payment for these items or services in a timelier manner than if CMS waited for the annual rulemaking process. We solicit public comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process. In Table 11 below, we summarize our proposed process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing their treatment under the hospital OPPS. We note that because the payment rates associated with codes effective July 1 are not available to us in time for incorporation into the Addenda of this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2013 OPPS quarterly update CR could not be included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site), while those codes based upon the April 2013 OPPS quarterly update CR are included in Addendum B. Nevertheless, we are requesting public comments on the codes included in the July 2013 OPPS quarterly update CR and including these codes in the preamble of this proposed rule (we refer readers to Tables 13 and 14 for the July 2013 CPT and Level II HCPCS codes).

TABLE 11—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April I, 2013	Level II HCPCS Codes	April 1, 2013	CY 2014 OPPS/ASC proposed rule.	CY 2014 OPPS/ASC final rule with comment period.
July 1, 2013	Level II HCPCS Codes	July 1, 2013	CY 2014 OPPS/ASC proposed rule.	CY 2014 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2013	CY 2014 OPPS/ASC proposed rule.	CY 2014 OPPS/ASC final rule with comment period.
October 1, 2013	Level II HCPCS Codes	October 1, 2013	CY 2014 OPPS/ASC final rule with comment period.	CY 2015 OPPS/ASC final rule with comment period.
January 1, 2014	Level II HCPCS Codes	January 1, 2014	CY 2014 OPPS/ASC final rule with comment period.	CY 2015 OPPS/ASC final rule with comment period.

TABLE 11—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES—Continued

OPPS Quarterly update CR	Type of code	Effective date	Comments sought	When finalized
	Category I and III CPT Codes.	January 1, 2014	CY 2014 OPPS/ASC final rule with comment period.	CY 2015 OPPS/ASC final rule with comment period.

This process is discussed in detail below. We have separated our discussion into two sections based on whether we are soliciting public comments in this CY 2014 OPPS/ASC proposed rule or whether we will be soliciting public comments in the CY 2014 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2013 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2013. We also sought public comments in the CY 2013 OPPS/ASC final rule with comment period on the new Level II HCPCS codes that were effective October 1, 2012. These new codes, with an effective date of October 1, 2012, or January 1, 2013, were flagged with comment indicator ''NI'' (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) in Addendum B to the CY 2013 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and an APC and payment rate, if applicable, which were subject to public comment following publication of the CY 2013 OPPS/ASC final rule with comment period. We will respond to public comments and finalize our interim OPPS treatment of these codes in the CY 2014 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New CY 2013 Level II HCPCS and CPT Codes Effective April 1, 2013 and July 1, 2013 for Which We Are Soliciting Public Comments in This CY 2014 OPPS/ASC Proposed Rule

Through the April 2013 OPPS quarterly update CR (Transmittal 2664, Change Request 8228, dated March 1, 2013), and the July 2013 OPPS quarterly update CR (Transmittal 2718, Change Request 8338, dated June 7, 2013), we recognized several new HCPCS codes for separate payment under the OPPS. Effective April 1 and July 1 of CY 2013, we made effective 18 new Level II HCPCS codes and 6 Category III CPT codes. Specifically, 8 new Level II HCPCS codes were effective for the April 2013 quarterly update and another 10 new Level II HCPCS codes were effective for the July 2013 quarterly update for a total of 18. In addition, six new Category III CPT codes were effective for the July 2013 quarterly update. Of the 24 new HCPCS codes, we recognized for separate payment under the OPPS 14 new codes from the April and July 2013 OPPS quarterly updates.

Through the April 2013 OPPS quarterly update CR, we allowed separate payment for five new Level II HCPCS codes. Specifically, as displayed in Table 12 below, we provided separate payment for HCPCS codes C9130, C9297, C9298, C9734, and C9735. HCPCS codes Q0507, Q0508, and Q0509 were assigned to OPPS status indicator ''A'' to indicate that they are paid through another Medicare payment system other than the OPPS. Although HCPCS codes Q0507, Q0508, and Q0509 were effective April 1, 2013, they were previously described by HCPCS code Q0505, which was deleted on March 31, 2013.

TABLE 12—NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2013

CY 2013 HCPCS code	CY 2013 Long descriptor	Proposed CY 2014 status indicator	Proposed CY 2014 APC
C9130*	Injection, immune globulin (Bivigam), 500 mg	G	9130
C9297*	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
C9298*	Injection, ocriplasmin, 0.125 mg	G	9298
C9734#	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with or without magnetic resonance (MR) guidance.	S	0065
C9735	Anoscopy; with directed submucosal injection(s), any substance	T	0150
Q0507	Miscellaneous supply or accessory for use with an external ventricular assist device	A	N/A
Q0508	Miscellaneous supply or accessory for use with an implanted ventricular assist device	A	N/A
Q0509	Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A.	A	N/A

*The proposed payment rate for HCPCS codes C9130, C9297, and C9298 are based on ASP+6 percent.
#HCPCS code C9734 has been revised to delete the words ''or without'' from the long descriptor effective July 1, 2013.

In this CY 2014 OPPS/ASC proposed rule, we are soliciting public comments on the proposed status indicators and APC assignments, where applicable, for the Level II HCPCS codes listed in Table 12 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

Through the July 2013 OPPS quarterly update CR, we allowed separate payment under the OPPS for 5 of the 10 new Level II HCPCS codes effective July 1, 2013. Specifically, as displayed in Table 13 below, we allowed separate payment for HCPCS codes C9131, C9736, G0460, Q2050, and Q2051. We note that two of the Level II HCPCS Q-codes that were made effective July 1, 2013, were previously described by HCPCS J-codes that were separately payable under the hospital OPPS. First, the HCPCS Workgroup replaced HCPCS code J9002 (Injection, doxorubicin hydrochloride, liposomal, Doxil, 10mg) with new HCPCS code Q2050, effective July 1, 2013, to appropriately identify and pay for both the brand and generic

forms of doxorubicin hydrochloride liposome. Consequently, the status indicator for HCPCS code J9002 was changed to ''E'' (Not Payable by Medicare), effective July 1, 2013. Because HCPCS code Q2050 describes the same product as HCPCS code J9002, we continued its separate payment status and assigned HCPCS code Q2050 to status indicator ''K'' (Nonpass-through drugs and nonimplantable biological, including therapeutic radiopharmaceuticals; paid under OPPS; separate APC payment). We also continued to assign HCPCS code Q2050 to the same APC as HCPCS code J9002, specifically APC 7046 (Doxil injection), effective July 1, 2013.

Secondly, the HCPCS Workgroup replaced HCPCS codes J3487 (Injection, zoledronic acid (Zometa), 1 mg) and J3488 (Injection, zoledronic acid (Reclast), 1 mg) with one new HCPCS code, specifically Q2051, effective July 1, 2013, to appropriately identify and pay for both the brand and generic forms of zoledronic acid. Consequently, the status indicators for both HCPCS code J3487 and J3488 were changed to ''E,'' effective July 1, 2013, to indicate that these codes are not separately payable by Medicare. Because HCPCS code Q2051 describes the same product as HCPCS codes J3487 and J3488, we assigned HCPCS code Q2051 to separate payment status indicator ''K,'' effective July 1, 2013. Because HCPCS codes J3487 and J3488, which were assigned to two separate APCs, were replaced with only one code, we assigned HCPCS code Q2051 to a new APC to maintain data consistency for future rulemaking. Specifically, HCPCS code Q2051 is assigned to APC 1356 (Zoldedronic acid 1mg), effective July 1, 2013.

Of the 10 Level II HCPCS codes that were made effective July 1, 2013, we did not recognize for separate payment under the hospital OPPS five HCPCS codes. Specifically, HCPCS codes K0008, K0013, and K0900 are assigned to status indicator ''Y'' (Non-implantable durable medical equipment; not paid under OPPS); HCPCS code Q2033 is assigned to status indicator ''L'' (Not paid under OPPS; paid at reasonable cost); and HCPCS code Q0090 is assigned to status indicator ''E'' (Not payable/Non-covered by Medicare; not paid under OPPS).

Table 13 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2013. As stated above, the codes effective July 1, 2013, do not appear in Addendum B of this proposed rule, and, as a result, their proposed payment rates along with their proposed status indicators and proposed APC assignments, where applicable, for CY 2014 are provided in Table 13.

TABLE 13—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2013

CY 2013 HCPCS code	CY 2013 Long descriptor	Proposed CY 2014 status indicator	Proposed CY 2014 APC	Proposed CY 2014 payment rate
C9131*	Injection, ado-trastuzumab emtansine, 1 mg	G	9131	$29.40
C9736	Laparoscopy, surgical, radiofrequency ablation of uterine fibroid(s), including intraoperative guidance and monitoring, when performed.	T	0131	3,765.67
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment.	T	0013	83.85
K0008	Custom Manual Wheelchair Base	Y	N/A	N/A
K0013	Custom Motorized/Power Wheelchair Base	Y	N/A	N/A
K0900	Customized Durable Medical Equipment, Other Than Wheelchair	Y	N/A	N/A
Q0090	Levonorgestrel-Releasing Intrauterine Contraceptive System (SKYLA), 13.5 mg	E	N/A	N/A
Q2033	Influenza Vaccine, Recombinant Hemagglutinin Antigens, For Intramuscular Use (Flublok).	L	N/A	N/A
Q2050** ...	Injection, Doxorubicin Hydrochloride, Liposomal, Not Otherwise Specified, 10mg	K	7046	545.44
Q2051*** ..	Injection, Zoledronic Acid, Not Otherwise Specified, 1mg	K	1356	196.42

*The proposed payment rate for HCPCS code C9131 is based on ASP+6 percent.

**HCPCS code Q2050 replaced HCPCS code J9002, effective July 1, 2013. The status indicator for HCPCS code J9002 was changed to ''E'' (Not Payable by Medicare), effective July 1, 2013. The proposed payment rate for HCPCS code Q2050 is based on ASP+6 percent.

***HCPCS code Q2051 replaced HCPCS codes J3487 and J3488 effective July 1, 2013. The status indicator for HCPCS codes J3487 and J3488 was changed to ''E'' (Not Payable by Medicare), effective July 1, 2013. The proposed payment rate for HCPCS code Q2051 is based on ASP+6 percent.

For CY 2014, we are proposing to continue our established policy of recognizing Category I CPT vaccine codes for which FDA approval is imminent and Category III CPT codes that the AMA releases in January of each year for implementation in July through the OPPS quarterly update process. Under the OPPS, Category I CPT vaccine codes and Category III CPT codes that are released on the AMA Web site in January are made effective in July of the same year through the July OPPS quarterly update CR, consistent with the AMA's implementation date for the codes. For the July 2013 quarterly update, there were no new Category I CPT vaccine codes. However, we note that Level II HCPCS code Q2033, which is listed in Table 13, describes a flu vaccine that was effective July 1, 2013, and is separately payable by Medicare at reasonable cost.

Through the July 2013 OPPS quarterly update CR (Transmittal 2718, Change Request 8338, dated June 7, 2013), we allowed separate payment for four of the six new Category III CPT codes effective July 1, 2013. Specifically, as displayed in Table 14 below, we allowed separate payment for Category III CPT codes 0330T, 0331T, 0332T, and 0334T. We did not recognize for separate payment Category III CPT code 0329T because the device associated with this procedure has not received FDA approval. In addition, we did not recognize for separate payment Category III CPT code 0333T because this procedure is not covered by Medicare. As listed in Table 14, both CPT codes 0329T and 0333T are assigned to status indicator ''E'' (Not payable/Non-covered by Medicare; not paid under OPPS).

Table 14 below lists the Category III CPT codes that were implemented in July 2013, along with their proposed status indicators, proposed APC assignments, and proposed payment rates, where applicable, for CY 2014.

TABLE 14—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2013

CY 2013 CPT code	CY 2013 Long descriptor	Proposed CY 2014 status indicator	Proposed CY 2014 APC	Proposed CY 2014 payment rate
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report.	E	N/A	N/A
0330T	Tear film imaging, unilateral or bilateral, with interpretation and report	S	0230	$51.83
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment;.	S	0398	397.32
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT.	S	0398	397.32
0333T	Visual evoked potential, screening of visual acuity, automated	E	N/A	N/A
0334T	Sacroiliac joint stabilization for arthrodesis, percutaneous or minimally invasive (indirect visualization), includes obtaining and applying autograft or allograft (structural or morselized), when performed, includes image guidance when performed (eg, CT or fluoroscopic).	T	0208	4,171.56

We are soliciting public comments on the CY 2014 proposed status indicators and the proposed APC assignments and payment rates for the Level II HCPCS codes and the Category III CPT codes that were effective April 1, 2013, and July 1, 2013. These codes are listed in Tables 12, 13, and 14 of this proposed rule. We are proposing to finalize their status indicators and their APC assignments and payment rates, if applicable, in the CY 2014 OPPS/ASC final rule with comment period. Because the new Category III CPT and Level II HCPCS codes that become effective for July are not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include the codes, their proposed status indicators, proposed APCs (where applicable), and proposed payment rates (where applicable) in the preamble of the proposed rule but not in the Addenda to the proposed rule. These codes are listed in Tables 13 and 14, respectively, of this proposed rule. We are proposing to incorporate these codes into Addendum B to the CY 2014 OPPS/ASC final rule with comment period, which is consistent with our annual OPPS update policy. The Level II HCPCS codes implemented or modified through the April 2013 OPPS quarterly update CR and displayed in Table 12 are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site), where their proposed CY 2014 payment rates are also shown.

2. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2013 and New CPT and Level II HCPCS Codes That Will Be Effective January 1, 2014 for Which We Will Be Soliciting Public Comments in the CY 2014 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the OPPS for the following calendar year. These codes are released to the public through the CMS HCPCS Workgroup (for Level II HCPCS codes) and the AMA's Web sites (for CPT codes), and also through the January OPPS quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period updating the OPPS for the following calendar year. For CY 2014, these codes will be flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. In addition, the CPT and Level II HCPCS codes that will be effective January 1, 2014, will be flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period. Specifically, the interim status indicator and the APC assignment and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the final rule with comment period, and we respond to these comments in the OPPS/ASC final rule with comment period for the next calendar year's OPPS/ASC update. We are proposing to continue this process for CY 2014. Specifically, for CY 2014, we are proposing to include in Addendum B to the CY 2014 OPPS/ASC final rule with comment period the following new HCPCS codes:

- New Level II HCPCS codes effective October 1, 2013 that would be incorporated in the October 2013 OPPS quarterly update CR;
- New Category I and III CPT codes effective January 1, 2014 that would be incorporated in the January 2014 OPPS quarterly update CR; and
- New Level II HCPCS codes effective January 1, 2014 that would be incorporated in the January 2014 OPPS quarterly update CR.

As stated above, the October 1, 2013 and January 1, 2014 codes would be flagged with comment indicator ''NI'' in Addendum B to the CY 2014 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim OPPS payment status for CY 2014. We are proposing that their status indicators and their APC assignments and payment rates, if applicable, would be open to public comment and would be finalized in the CY 2015 OPPS/ASC final rule with comment period.

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in

§ 419.31 of the regulations. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices.

We have packaged into payment for each procedure or service within an APC group the costs associated with those items or services that are directly related to, and supportive of, performing the main independent procedures or furnishing the services. Therefore, we do not make separate payment for these packaged items or services. In general, according to the regulations at § 419.2(b), packaged items and services include, but are not limited to:

(1) Use of an operating suite, procedure room, or treatment room;

(2) Use of recovery room;

(3) Use of an observation bed;

(4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;

(5) Supplies and equipment for administering and monitoring anesthesia or sedation;

(6) Intraocular lenses (IOLs);

(7) Incidental services such as venipuncture;

(8) Capital-related costs;

(9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;

(10) Durable medical equipment that is implantable;

(11) Implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices;

(12) Costs incurred to procure donor tissue other than corneal tissue.

Significant revisions to the regulations at § 419.2(b) are being proposed. Further discussion of our packaging proposals is included in section II.A.3. of this proposed rule.

In CY 2008, we implemented composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service (72 FR 66650 through 66652). Under the CY 2013 OPPS (77 FR 68243 through 68258), we provided composite APC payments for 10 categories of services:

(1) Mental Health Services (APC 0034);

(2) Cardiac Electrophysiologic Evaluation and Ablation (APC 8000);

(3) Low Dose Rate (LDR) Prostate Brachytherapy (APC 8001);

(4) Level I Extended Assessment & Management Composite (APC 8002);

(5) Level II Extended Assessment & Management Composite (APC 8003);

(6) Ultrasound (APC 8004);

(7) CT and CTA without Contrast (APC 8005);

(8) CT and CTA with Contrast (APC 8006);

(9) MRI and MRA without Contrast Composite (APC 8007); and

(10) MRI and MRA with Contrast Composite (APC 8008)

Further discussion of composite APCs is included in section II.A.2.f. of this proposed rule.

Under the OPPS, we generally pay for hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. Each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in new proposed APC 0634 (Hospital Clinic Visits). The APC relative payment weights are scaled to new proposed APC 0634 because it is the hospital clinic visit APC and because clinic visits are among the most frequently furnished services in the hospital outpatient setting. We refer readers to section VII. (Proposed OPPS Payment for Hospital Outpatient Visits) of this proposed rule for further discussion of the establishment of new proposed APC 0634.

Section 1833(t)(9)(A) of the Act requires the Secretary to review, on a recurring basis occurring no less than annually, and revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights (the HOP Panel recommendations for specific services for the CY 2014 OPPS and our responses to them are discussed in the relevant specific sections throughout this proposed rule).

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act).

2. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the cost of the highest cost item or service within an APC group is more than 2 times greater than the cost of the lowest cost item or service within that same group. In making this determination, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant HCPCS codes for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost. In this proposed rule, we are proposing to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services, for CY 2014.

We have identified APCs with 2 times rule violations for which we are proposing changes to their HCPCS

codes' APC assignments in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of the CY 2014 OPPS/ASC proposed rule. Rather, it is published and made available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. In these cases, to eliminate a 2 times rule violation or to improve clinical and resource homogeneity, we are proposing to reassign the codes to APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2014 included in this proposed rule are related to changes in costs of services that were observed in the CY 2012 claims data newly available for CY 2014 ratesetting. We also are proposing changes to the status indicators for some codes that are not specifically and separately discussed in this proposed rule. In these cases, we are proposing to change the status indicators for some codes because we believe that another status indicator would more accurately describe their payment status from an OPPS perspective based on the policies that we are proposing for CY 2014. In addition, we are proposing to rename existing APCs or create new clinical APCs to complement proposed HCPCS code reassignments. Addendum B of this CY 2014 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those HCPCS codes for which we are proposing a change to the APC assignment or status indicator, or both, that were initially assigned in the April 2013 Addendum B Update (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*).

3. Proposed Exceptions to the 2 Times Rule

As discussed earlier, we may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases such as low-volume items and services. Taking into account the APC changes that we are proposing for CY 2014, we reviewed all the APCs to determine which APCs would not satisfy the 2 times rule. Then we used the following criteria to decide whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18457 and 18458).

We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we generally accept the Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 15 of this proposed rule lists 10 APCs that we are proposing to exempt from the 2 times rule for CY 2014 based on the criteria cited above and based on claims data processed from January 1, 2012, through December 31, 2012. For the final rule with comment period, we plan to use claims data for dates of service between January 1, 2012, and December 31, 2012, that were processed on or before June 30, 2013, and updated CCRs, if available. Based on the CY 2012 claims data, we found 10 APCs with 2 times rule violations. We applied the criteria as described earlier to identify the APCs that we are proposing as exceptions to the 2 times rule for CY 2014, and identified 10 APCs that meet the criteria for exception to the 2 times rule for this proposed rule. We have not included in this count those APCs where a 2 times rule violation is not a relevant concept, such as APC 0375 (Ancillary Outpatient Services when Patient Expires), with an APC cost set based on multiple procedure claims. Therefore, we have identified only APCs, including those with criteria-based costs, those APCs listed under section II.A.2.f. of this proposed rule, with 2 times rule violations. These proposed APC exceptions are listed in Table 15 below.

TABLE 15—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2014

APC	Description
0057	Bunion Procedures.
0060	Manipulation Therapy.
0075	Level V Endoscopy Upper Airway.
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices.
0148	Level I Anal/Rectal Procedures.
0272	Fluoroscopy.
0278	Diagnostic Urography.
0330	Dental Procedures.
0402	Level II Nervous System Imaging.
0690	Level I Electronic Analysis of Devices.

The proposed costs for hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

C. Proposed OPPS APC-Specific Policies

1. Intraoperative Radiation Therapy (IORT) Related Services (APCs 0028 and 0065)

HCPCS code C9726 (Placement and removal (if performed) of applicator into breast for radiation therapy) was created effective January 1, 2006 to describe the service of placing and removing (if performed) an applicator into the breast for radiation therapy. The service was brought to our attention by means of a New Technology APC application, and we created HCPCS code C9726 because there were no HCPCS codes that described this service. HCPCS code C9726 is assigned to APC 0028, which has a CY 2013 payment rate of $1,862.77. Based on our CY 2014 proposed rule claims data, APC 0028 has a geometric mean cost of approximately $2,147, and HCPCS code C9726 has a geometric mean cost of

approximately $2,165 based upon 8 single claims.

The AMA's CPT Editorial Panel created two new Category I CPT codes for intraoperative radiation therapy (IORT) treatment delivery, effective January 1, 2012: CPT codes 77424 (Intraoperative radiation treatment delivery, x-ray, single treatment session) and 77425 (Intraoperative radiation treatment delivery, electrons, single treatment session). For CY 2013, we finalized a policy to assign these CPT codes to APC 0065 (IORT, MRgFUS, and MEG), with a CY 2013 payment rate of $978.25 because we believed these IORT service codes were similar to services assigned to APC 0065 in terms of clinical characteristics, and the range of estimated costs for IORT services (77 FR 68345).

CPT codes 77424 and 77425 describe the placement and removal (if performed) of an applicator into the breast for radiation therapy, as well as the delivery of radiation therapy when performed intraoperatively, and HCPCS code C9726 is no longer required to report the placement and removal of the applicator. Therefore, we are proposing to delete HCPCS code C9726, effective January 1, 2014. Under this proposal, hospitals would report the costs of the service to place and remove (if performed) an applicator into the breast for radiation therapy, as well as the delivery of radiation therapy when performed intraoperatively, with CPT codes 77424 and 77425, which we are proposing to maintain assignment to APC 0065. We are inviting public comments on this proposal.

2. Proton Beam Radiation Therapy (APCs 0664 and 0667)

APC 0664 (Level I Proton Beam Radiation Therapy) includes two procedures, CPT code 77520 (Proton treatment delivery; simple, without compensation) with an estimated cost of approximately $417 (based on 217 single claims of 218 total claims submitted for CY 2012), and CPT code 77522 (Proton treatment delivery; simple, with compensation) with an estimated cost of approximately $883 (based on 10,629 single claims of 11,260 total claims submitted for CY 2012). APC 0667 (Level II Proton Beam Radiation Therapy) also includes two procedures: CPT code 77523 (Proton treatment delivery, intermediate), with an estimated cost of approximately $687 (based on 6,707 single claims of 7,104 total claims submitted for CY 2012); and CPT code 77525 (Proton treatment delivery, complex), with an estimated cost of approximately $1,044 (based on 438 single claims of 547 total claims submitted for CY 2012). Based on these CY 2012 claims data, the estimated cost of APC 0664 is approximately $870, and the estimated cost of APC 0667 is approximately $705.

The payment rates for proton beam radiation therapy services are set annually based on claims data according to the standard OPPS ratesetting methodology. Based on our updated data for CY 2014, we noted a violation of the 2 times rule in APC 0664. As we discuss in section III.B. of this proposed rule, a 2 times violation occurs when the cost of the highest cost item or service within an APC group is more than 2 times greater than the cost of the lowest cost item or service within that same group. In making this determination, we consider only codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant. If neither of these claims thresholds are met, there is not a 2 times violation even if the highest cost item or service is more than 2 times greater than the cost of the lowest cost item or service in the APC. In prior years, even though the cost of CPT code 77522 was more than 2 times the cost of CPT code 77520, there was no 2 times violation in APC 0664 because the claims volume for CPT code 77520 did not meet either of the claims volume tests discussed above (72 FR 66719; 75 FR 71901; and 77 FR 68341). However, for CY 2014, the claims volume for CPT code 77520 increased such that there is a 2 times violation within APC 0664, with the single claims for CPT code 77520 greater than 99 and contributing 2 percent of the single claims used to establish the cost of APC 0664.

To resolve the 2 times violation, we are proposing to reassign CPT codes 77520 and 77522 from APC 0664 to APC 0667, and to revise the title of APC 0667 to ''Proton Beam Radiation Therapy,'' which would now include all proton beam radiation therapy services. We also are proposing to delete APC 0664. The estimated cost of the new APC 0667 is approximately $998, which would be the payment rate for each of the four proton beam radiation therapy services. We are inviting public comments on this proposal.

3. Stereotactic Radiosurgery (SRS) Services (APCs 0066 and 0067)

Since 2001, we have distinguished the various methods of delivery of stereotactic radiosurgery (SRS) with HCPCS G-codes. SRS includes two different source types, specifically, Cobalt-60 and linear accelerator (linac). Among the linac-based SRS devices, the HCPCS G-codes distinguish between robotic and nonrobotic (66 FR 59865). In 2007 new CPT codes were established for SRS, and at that time, we recognized one of the three new CPT codes for SRS for separate payment under the OPPS, but we did not replace all of the HCPCS G-codes for SRS with the new CPT codes because we believed that the distinctions reflected in the HCPCS G-codes should be maintained for APC assignment purposes. Specifically, in 2007 we replaced HCPCS code G0243 (Multi-source photon stereotactic radiosurgery, delivery including collimator changes and custom plugging, complete course of treatment, all lesions) with CPT code 77371 because this CPT code corresponded directly to procedures for HCPCS code G0243. We refer readers to the CY 2007 OPPS final rule (71 FR 68023 through 68026) for a detailed discussion of the history of the SRS codes.

Since 2007, HCPCS G-codes G0173, G0251, G0339, G0340, and CPT code 77371 have been the codes used in the OPPS to describe SRS treatment delivery procedures. However, SRS techniques and equipment have evolved and advanced over time. In light of these considerations, we have reexamined the HCPCS G-codes and CPT codes for SRS with the intent of identifying the codes that would best capture the significant differences between the various procedures while eliminating unnecessary complexity, redundancy, and outdated distinctions that no longer represent meaningful distinctions, given current technology and clinical practice. Based on our review of the current SRS technology, it is our understanding that most current linac-based SRS technology incorporates some type of robotic feature. Therefore, we believe that it is no longer necessary to continue to distinguish robotic versus nonrobotic linac-based SRS through the HCPCS G-codes. For CY 2014, we are proposing to replace the existing four SRS HCPCS G-codes G0173, G0251, G0339, and G0340, with the SRS CPT codes 77372 and 77373. We believe that utilizing all of the CPT codes for SRS (77371, 77372, and 77373) will more accurately capture the most significant distinctions between the various SRS procedures that are currently used today, namely: (1) Cobalt-60 versus linac; and (2) single session cranial treatment versus fractionated treatments.

Table 16 below shows the complete list of HCPCS G-codes and CPT codes for SRS, along with their long descriptors. The table also shows the proposed CPT codes and their

associated status indicators and APC assignments for the current HCPCS G-codes for SRS that we are proposing to replace. We are proposing to assign CPT code 77373 as the only code assigned to APC 0066, which we are proposing to rename ''Level I Stereotactic Radiosurgery.'' We are proposing to assign both of the single session cranial treatment codes (CPT codes 77371 and 77372) as the only two codes assigned to APC 0067, which we are proposing to rename ''Level II Stereotactic Radiosurgery.'' We believe that the high degree of clinical similarity of CPT codes 77371 and 77372 supports the proposed grouping of these procedures together in the proposed renamed APC 0067 (Level II Stereotactic Radiosurgery). The CY 2014 APC proposed payment rates for the CPT codes for SRS can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). We are proposing to finalize their status indicators and their APC assignments and payment rates in the CY 2014 OPPS/ASC final rule with comment period.

In addition, although the SRS HCPCS G-codes will no longer be separately payable under the OPPS, the codes will remain active in the MPFS for CY 2014. Consequently, we are proposing to reassign the HCPCS G-codes for SRS to OPPS status indicator ''B'' (Alternative code may be available under the OPPS) for CY 2014.

TABLE 16—PROPOSED SEPARATELY PAYABLE STEREOTACTIC RADIOSURGERY (SRS) SERVICES FOR CY 2014

CY 2013 CPT code	Long descriptor	CY 2014 CPT code	Long descriptor	CY 2014 SI	CY 2014 APC
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based.	77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based.	S	0067
G0173	Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session.	77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based.	S	0067
G0251	Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment.	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions.	S	0066
G0339* ..	Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment.				
G0340	Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment.				

*Although not reflected in the above table (in order to avoid confusion), single session cranial cases currently billed with HCPCS code G0339 would be billed with CPT code 77372 beginning in CY 2014. Any other reporting of HCPCS code G0339 (other than single session cranial cases) would be reported beginning in CY 2014 with CPT code 77373.

IV. Proposed OPPS Payment for Devices

A. Proposed Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

a. Background

Section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. This pass-through payment eligibility period begins with the first date on which transitional pass-through payments may be made for any medical device that is described by the category. We may establish a new device category for pass-through payment in any quarter. Under our established policy, we base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category, which is the first date on which pass-through payment may be made for any medical device that is described by such category. We propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update.

We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763). Brachytherapy sources, which are now separately paid in accordance with section 1833(t)(2)(H) of the Act, are an exception to this established policy.

There currently are three device categories eligible for pass-through payment. These device categories are described by HCPCS codes C1830 (Powered bone marrow biopsy needle) and C1840 (Lens, intraocular (telescopic)), which we made effective for pass-through payment as of October 1, 2011; and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)), which we made effective for pass-through payment as of January 1, 2012. Recognizing that these three device categories were eligible for at least 2, but not more than 3, years of pass-through status, in the CY 2013 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for all three of these HCPCS codes, which will expire after December 31, 2013 (77 FR 68352). Therefore, in accordance with our established policy, after December 31, 2013, we will

package the respective costs of the HCPCS codes C1830, C1840, and C1886 devices into the costs of the procedures with which the devices are reported in the hospital claims data used in OPPS ratesetting.

b. Proposed CY 2014 Policy

As previously stated, we have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763). In the case of device category C1840, we are proposing that the device costs be packaged only when billed with CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens), which became effective on July 1, 2012. We announced the policy that device category C1840 must be billed with CPT code 0308T, effective July 1, 2012, in Transmittal 2483, dated June 8, 2012. CPT code 0308T is currently assigned to APC 0234 (Level IV Anterior Segment Eye Procedures), which has a proposed geometric mean cost of approximately $1,794. When the CPT code C1840 device costs are packaged into the cost of CPT code 0308T (and the equivalent procedure described by HCPCS code C9732 for the first half of 2012), the proposed mean cost of the procedure is approximately $15,249. Based on this mean cost for CPT code 0308T, we are proposing to create new APC 0351 (Level VII Anterior Segment Eye Procedures), and to assign CPT code 0308T to this APC, which has a proposed mean cost of approximately $15,249. The mean cost for CY 2014 that will be reported in the final rule for this new APC will depend on the mean cost of CPT code 0308T (including the cost of HCPCS code C1840) as calculated using claims data available for the final rule.

With the expiration of these three device categories at the end of CY 2013, there are no currently active categories for which we would propose expiration of pass-through status in CY 2014. If we create new device categories for pass-through payment status during the remainder of CY 2013 or during CY 2014, we will propose future expiration dates in accordance with the statutory requirement that they be eligible for pass-through payments for at least 2, but not more than 3, years from the date on which pass-through payment for any medical device described by the category may first be made.

2. Proposed Provisions for Reducing Transitional Pass-Through Payments To Offset Costs Packaged Into APC Groups

a. Background

Section 1833(t)(6)(D)(ii) of the Act sets the amount of additional pass-through payment for an eligible device as the amount by which the hospital's charges for a device, adjusted to cost (the cost of the device) exceeds the portion of the otherwise applicable Medicare outpatient department fee schedule amount (the APC payment amount) associated with the device. We have an established policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904) for purposes of estimating the portion of the otherwise applicable APC payment amount associated with pass-through devices. For eligible device categories, we deduct an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, from the charges adjusted to cost for the device, as provided by section 1833(t)(6)(D)(ii) of the Act, to determine the eligible device's pass-through payment amount. We have consistently used an established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC rates (72 FR 66751 through 66752). We establish and update the applicable device APC offset amounts for eligible pass-through device categories through the transmittals that implement the quarterly OPPS updates.

Currently, we have published a list of all procedural APCs with the CY 2013 portions (both percentages and dollar amounts) of the APC payment amounts that we determine are associated with the cost of devices on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The dollar amounts are used as the device APC offset amounts. In addition, in accordance with our established practice, the device APC offset amounts in a related APC are used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices, as specified in our regulations at § 419.66(d).

Beginning in CY 2010, we include packaged costs related to implantable biologicals in the device offset calculations in accordance with our policy that the pass-through evaluation process and payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only (74 FR 60476).

b. Proposed CY 2014 Policy

We are proposing to continue, for CY 2014, our established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to (that is, reflect) the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC payment rates. We are proposing to continue our policy, for CY 2014, that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only. The rationale for this policy is provided in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477). We also are proposing to continue our established policies for calculating and setting the device APC offset amounts for each device category eligible for pass-through payment. In addition, we are proposing to continue to review each new device category on a case-by-case basis to determine whether device costs associated with the new category are already packaged into the existing APC structure. If device costs packaged into the existing APC structure are associated with the new category, we are proposing to deduct the device APC offset amount from the pass-through payment for the device category. As stated earlier, these device APC offset amounts also would be used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices (§ 419.66(d)).

For CY 2014, we also are proposing to continue our policy established in CY 2010 to include implantable biologicals in our calculation of the device APC offset amounts. In addition, we are

proposing to continue to calculate and set any device APC offset amount for any new device pass-through category that includes a newly eligible implantable biological beginning in CY 2014 using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment, and to include the costs of implantable biologicals in the calculation of the device APC offset amounts.

In addition, we are proposing to update the list of all procedural APCs with the final CY 2014 portions of the APC payment amounts that we determine are associated with the cost of devices on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* so that this information is available for use by the public in developing potential CY 2014 device pass-through payment applications and by CMS in reviewing those applications.

3. Proposed Changes to Device Pass-Through Criteria: Integral and Subordinate Criterion

We established a number of specific criteria that new medical devices must meet to be considered eligible for pass-through payments under section 1833(t)(6) of the Act (42 CFR 419.66; 65 FR 18480 and 65 FR 47672 through 47674). In this proposed rule, we are proposing to change one of these criteria for device pass-through payment, described at § 419.66(b)(3), which requires that a device ''is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital'' (65 FR 47674).

Regarding the existing regulation at § 419.66(b)(3), applicants for device pass-through status have continued to ask what is meant by the phrase ''integral and subordinate part of the service furnished,'' and more specifically, what the terms ''integral'' and ''subordinate'' mean. These terms have not been specifically defined or described in prior regulatory language, preamble, or guidance. In an effort to reduce further confusion and ensure all applicants understand the intent of the existing regulation, we are proposing to provide guidance on the meaning of the term ''integral'' and delete the term ''subordinate'' from the existing regulation in this proposed rule. We have interpreted the term ''integral'' to mean that the device is necessary to furnish or deliver the primary procedure with which it is used. For example, a pacemaker is integral to the procedure of implantation of a pacemaker. We have interpreted the accompanying term ''subordinate'' in conjunction with the term ''integral,'' in that a ''subordinate'' device is dependent upon the overall procedure of implanting the device, and we have not interpreted the term separately, or applied the term ''subordinate'' as a separate criterion. Because of confusion among pass-through status applicants regarding the use of both terms ''integral'' and ''subordinate,'' and because we do not believe it is necessary that the regulation specifically state that a device must be subordinate to the procedure, in addition to the requirement that a device be integral to the procedure, and have not treated ''subordinate'' as a separate criterion, as previously explained, we are proposing to delete the term ''subordinate'' from this criterion's regulatory text under existing § 419.66(b)(3). The proposed revised § 419.66(b)(3) regulatory language reads: ''The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, whether or not it remains with the patient when the patient is released from the hospital.''

B. Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

1. Background

To ensure equitable payment when the hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals are instructed to report no cost/full credit cases using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, the hospital is instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, the hospital is instructed to report as the device charge the difference between its usual charge for the device being implanted and its usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals are instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' payment adjustment policies (72 FR 66743 through 66749).

2. Proposed Policy for CY 2014

Beginning in CY 2014, we are proposing to modify our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy has been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we are proposing to reduce OPPS payment, for the applicable APCs listed below in Table 17, by the full or partial credit a provider receives for a replaced device. Specifically, under this proposed policy for CY 2014, hospitals would be required to report the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device listed in Table 18 that is 50 percent or greater than the cost of the device. Under this proposal, hospitals would no longer be required to append the ''FB'' or ''FC'' modifier when receiving a device at no cost or with a full or partial credit.

For CY 2014, we are proposing to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which our modified CY 2014 policy applies (71 FR 68072 through 68077). Specifically: (1) All procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least

temporarily); and (3) the device offset amount must be significant, which, for purposes of this policy, is defined as exceeding 40 percent of the APC cost. We also are proposing to continue to restrict the devices to which the APC payment adjustment would apply to a specific set of costly devices to ensure that the adjustment would not be triggered by the implantation of an inexpensive device whose cost would not constitute a significant proportion of the total payment rate for an APC. We continue to believe these criteria are appropriate because no cost devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost.

We examined the offset amounts calculated from the CY 2014 proposed rule data and the clinical characteristics of the proposed CY 2014 APCs to determine which APCs would meet the criteria for CY 2014. Based on the CY 2012 claims data available for this proposed rule, we are not proposing any changes to the APCs and devices to which this proposed modified policy would apply.

Table 17 below lists the proposed APCs to which the proposed modified payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2014.

Table 18 below lists the proposed devices to which the proposed modified payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2014. We are proposing to update the lists of APCs and devices to which the proposed modified no cost/full credit and partial credit device adjustment policy would apply for CY 2014, consistent with the three criteria discussed earlier in this section, based on the final CY 2012 claims data available for the CY 2014 OPPS/ASC final rule with comment period.

TABLE 17—PROPOSED APCS TO WHICH THE PROPOSED MODIFIED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2014

Proposed CY 2014 APC	Proposed CY 2014 APC title
0039	Level I Implantation of Neurostimulator Generator.
0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.
0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes.
0082	Coronary or Non-Coronary Atherectomy.
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization.
0085	Level II Electrophysiologic Procedures.
0086	Level III Electrophysiologic Procedures.
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.
0090	Level I Insertion/Replacement of Permanent Pacemaker.
0104	Transcatheter Placement of Intracoronary Stents.
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes.
0107	Level I Implantation of Cardioverter-Defibrillators (ICDs).
0108	Level II Implantation of Cardioverter-Defibrillators (ICDs).
0227	Implantation of Drug Infusion Device.
0229	Level II Endovascular Revascularization of the Lower Extremity.
0259	Level VII ENT Procedures.
0293	Level VI Anterior Segment Eye Procedures.
0315	Level II Implantation of Neurostimulator Generator.
0318	Implantation of Neurostimulator Pulse Generator and Electrode.
0319	Level III Endovascular Revascularization of the Lower Extremity.
0385	Level I Prosthetic Urological Procedures.
0386	Level II Prosthetic Urological Procedures.
0425	Level II Arthroplasty or Implantation with Prosthesis.
0648	Level IV Breast Surgery.
0654	Level II Insertion/Replacement of Permanent Pacemaker.
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing.
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0674	Prostate Cryoablation.
0680	Insertion of Patient Activated Event Recorders.

TABLE 18—PROPOSED DEVICES TO WHICH THE PROPOSED MODIFIED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2014

CY 2014 Device HCPCS code	CY 2014 Short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.

TABLE 18—PROPOSED DEVICES TO WHICH THE PROPOSED MODIFIED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2014—Continued

CY 2014 Device HCPCS code	CY 2014 Short descriptor
C1728	Cath, brachytx seed adm.
C1764	Event recorder, cardiac.

TABLE 18—PROPOSED DEVICES TO WHICH THE PROPOSED MODIFIED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2014—Continued

CY 2014 Device HCPCS code	CY 2014 Short descriptor
C1767	Generator, neurostim, imp.
C1771	Rep dev, urinary, w/sling.

TABLE 18—PROPOSED DEVICES TO WHICH THE PROPOSED MODIFIED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2014—Continued

CY 2014 Device HCPCS code	CY 2014 Short descriptor
C1772	Infusion pump, programmable.
C1776	Joint device (implantable).
C1777	Lead, AICD, endo single coil.
C1778	Lead, neurostimulator.
C1779	Lead, pmkr, transvenous VDD.
C1785	Pmkr, dual, rate-resp.
C1786	Pmkr, single, rate-resp.
C1789	Prosthesis, breast, imp.
C1813	Prosthesis, penile, inflatab.
C1815	Pros, urinary sph, imp.
C1820	Generator, neuro rechg bat sys.
C1881	Dialysis access system.
C1882	AICD, other than sing/dual.
C1891	Infusion pump, non-prog, perm.
C1895	Lead, AICD, endo dual coil.
C1896	Lead, AICD, non sing/dual.
C1897	Lead, neurostim, test kit.
C1898	Lead, pmkr, other than trans.
C1899	Lead, pmkr/AICD combination.
C1900	Lead coronary venous.
C2619	Pmkr, dual, non rate-resp.
C2620	Pmkr, single, non rate-resp.
C2621	Pmkr, other than sing/dual.
C2622	Prosthesis, penile, non-inf.
C2626	Infusion pump, non-prog, temp.
C2631	Rep dev, urinary, w/o sling.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals (also referred to as biologics). As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this provision requires the Secretary to make additional payments to hospitals for: current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107–186); current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to drugs or biologicals that are outpatient hospital services under Part B for which payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments are also provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2014 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this proposed rule, which are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. If the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the pass-through payment amount is determined by the Secretary to be equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary. However, we note that the Part B drug CAP program has been postponed since CY 2009, and such a program has not been reinstated for CY 2014.

This methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

The pass-through application and review process for drugs and biologicals is explained on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.*

2. Proposed Drugs and Biologicals With Expiring Pass-Through Status in CY 2013

We are proposing that the pass-through status of 15 drugs and biologicals would expire on December 31, 2013, as listed in Table 19 below. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2013. These drugs and biologicals were approved for pass-through status on or before January 1, 2012. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status, specifically diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, and our new proposed groups of policy packaged products described in section II.A.3. of this proposed rule, namely drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure, our standard methodology for providing payment for drugs and biologicals with expiring pass-through status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed at $90 for CY 2014), as discussed further in section V.B.2. of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we would provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for

CY 2014, as discussed further in section V.B.3. of this proposed rule).

TABLE 19—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2013

Proposed CY 2014 HCPCS code	Proposed CY 2014 long descriptor	Proposed CY 2014 SI	Proposed CY 2014 APC
A9584	Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries	N	N/A
C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	N	9285
J0131	Injection, acetaminophen, 10 mg	N	9283
J0485	Injection, belatacept, 1 mg	K	9286
J0490	Injection, belimumab, 10 mg	K	1353
J0638	Injection, canakinumab, 1mg	K	1311
J0712	Injection, ceftaroline fosamil, 10 mg	N	9282
J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg.	K	0947
J2507	Injection, pegloticase, 1 mg	K	9281
J7180	Injection, factor xiii (antihemophilic factor, human), 1 i.u	K	1416
J9042	Injection, brentuximab vedotin, 1 mg	K	9287
J9179	Injection, eribulin mesylate, 0.1 mg	K	1426
J9228	Injection, ipilimumab, 10 mg	K	9284
Q4124	Oasis Ultra Tri-Layer matrix, per square centimeter	N	9365
Q4131	EpiFix, per square centimeter	N	9366

3. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2014

We are proposing to continue pass-through status in CY 2014 for 18 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2013. These drugs and biologicals, which were approved for pass-through status between April 1, 2012 and July 1, 2013, are listed in Table 20 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through April 1, 2013 are assigned status indicator ''G'' in Addenda A and B of this proposed rule. Addenda A and B of this proposed rule are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the physician's office payment rate of ASP+6 percent. We believe it is consistent with the statute to propose to continue to provide payment for drugs and biologicals with pass-through status at a rate of ASP+6 percent in CY 2014, the amount that drugs and biologicals receive under section 1842(o) of the Act.

Therefore, for CY 2014, we are proposing to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2014. We are proposing that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2014 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, proposed at ASP+6 percent, is $0.

In the case of pass-through for policy packaged drugs (which include contrast agents, diagnostic radiopharmaceuticals, anesthesia drugs, and our new proposed groups of policy packaged products described in section II.A.3. of this proposed rule, namely drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure), we are proposing that their pass-through payment amount would be equal to ASP+6 percent for CY 2014 because, if not on pass-through status, payment for these products would be packaged into the associated procedure.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2014 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 42722 and 42723).

In CY 2014, as is consistent with our CY 2013 policy for diagnostic and therapeutic radiopharmaceuticals, we are proposing to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through status based on the ASP methodology. As stated above, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2014, we are proposing to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we are proposing to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information is also not available, we are proposing to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

As discussed in more detail in section II.A.3. of this proposed rule, over the last 6 years, we implemented a policy whereby payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs is packaged into payment for the associated procedure.

We are proposing to continue the packaging of these items and also are proposing new groups of policy packaged products described in section II.A.3. of this proposed rule, namely drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure, regardless of their per day cost, in CY 2014. As stated earlier, pass-through payment is the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Because payment for a drug that is policy packaged would otherwise be packaged if the product did not have pass-through status, we believe the otherwise applicable OPPS payment amount would be equal to the policy packaged drug APC offset amount for the associated clinical APC in which the drug or biological is utilized. The proposed calculation of the policy packaged drug APC offset amounts is described in more detail in section IV.A.2. of this proposed rule. It follows that the copayment for the nonpass-through payment portion (the otherwise applicable fee schedule amount that we would also offset from payment for the drug or biological if a payment offset applies) of the total OPPS payment for those drugs and biologicals would, therefore, be accounted for in the copayment for the associated clinical APC in which the drug or biological is used.

According to section 1833(t)(8)(E) of the Act, the amount of copayment associated with pass-through items is equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, as we did in CY 2013, we are proposing to continue to set the associated copayment amount to zero for CY 2014 for pass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs that would otherwise be packaged if the item did not have pass-through status. We also are proposing to set the associated copayment amount to zero for the additional categories of policy-packaged products proposed for CY 2014 described in section II.A.3. of this proposed rule.

The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical, contrast agent, anesthesia drug, and the additional categories of policy-packaged products proposed for CY 2014 is not subject to a copayment according to the statute. Therefore, we are proposing to not publish a copayment amount for these items in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

For CY 2013, we estimated the OPPS pass-through payment for drugs and biologicals to be $22 million. Our proposed OPPS pass-through payment estimate for drugs and biologicals in CY 2014 is $1 million, which is discussed in section VI.B. of this proposed rule. The 18 drugs and biologicals that we are proposing to continue on pass-through status for CY 2014 or have been granted pass-through status as of July 2013 are displayed in Table 20 below.

TABLE 20—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2014

Proposed CY 2014 HCPCS code	CY 2014 Long descriptor	Proposed CY 2014 SI	Proposed CY 2014 APC
C9130	Injection, immune globulin (Bivigam), 500 mg	G	9130
C9131* ...	Injection, ado-trastuzumab emtansine, 1 mg	G	9131
C9290	Injection, bupivicaine liposome, 1 mg	G	9290
C9292	Injection, pertuzumab, 10 mg	G	9292
C9293	Injection, glucarpidase, 10 units	G	9293
C9294	Injection, taliglucerase alfa, 10 units	G	9294
C9295	Injection, carfilzomib, 1 mg	G	9295
C9296	Injection, ziv-aflibercept, 1 mg	G	9296
C9297	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
C9298	Injection, ocriplasmin, 0.125 mg	G	9298
J0178	Injection, aflibercept, 1 mg vial	G	1420
J0716	Injection, centruroides (scorpion) immune f(ab)2, up to 120 milligrams	G	1431
J7315	Mitomycin, ophthalmic, 0.2 mg	G	1448
J9019	Injection, asparaginase (erwinaze), 1,000 iu	G	9289
Q4122* ...	Dermacell, per square centimeter	G	1419
Q4127	Talymed, per square centimeter	G	1449
Q4132	Grafix core, per square centimeter	G	9368
Q4133	Grafix prime, per square centimeter	G	9369

*Because the payment rates associated with these codes effective July 1, 2013 are not available to us in time for incorporation into the Addenda of this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2013 OPPS quarterly update CR could not be included in Addendum B to this proposed rule.

4. Proposed Provisions for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals; Contrast Agents; Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure; and Drugs and Biologicals That Function as Supplies or Devices When Used in a Surgical Procedure to Offset Costs Packaged Into APC Groups

a. Background

Prior to CY 2008, diagnostic radiopharmaceuticals and contrast agents were paid separately under the OPPS if their mean per day costs were greater than the applicable year's drug packaging threshold. In CY 2008 (72 FR 66768), we began a policy of packaging payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents as ancillary and supportive items and services into their associated nuclear medicine procedures. Therefore, beginning in CY 2008, nonpass-through diagnostic radiopharmaceuticals and contrast agents were not subject to the annual OPPS drug packaging threshold to determine their packaged or separately payable payment status, and instead all nonpass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy. For CY 2014, we are proposing to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs and to begin packaging all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure, as discussed in section II.A.3. of this proposed rule.

b. Proposed Payment Offset Policy for Diagnostic Radiopharmaceuticals

As previously noted, radiopharmaceuticals are considered to be drugs for OPPS pass-through payment purposes. As described above, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. There is currently one radiopharmaceutical with pass-through status under the OPPS, HCPCS code A9584 (Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries). This product, which is presently referred to using HCPCS code A9584, was granted pass-through status using HCPCS code C9406 beginning July 1, 2011, and we are proposing that its pass-through status would expire on December 31, 2013. We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for this product. As described earlier in section V.A.3. of this proposed rule, we are proposing that new pass-through diagnostic radiopharmaceuticals would be paid at ASP+6 percent, while those new pass-through diagnostic radiopharmaceuticals without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for diagnostic radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor radiopharmaceuticals in order to ensure no duplicate radiopharmaceutical payment is made. In CY 2009, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals when considering a new diagnostic radiopharmaceutical for pass-through payment (73 FR 68638 through 68641). Specifically, we use the policy packaged drug offset fraction for APCs containing nuclear medicine procedures, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy packaged drugs divided by the cost from single procedure claims in the APC.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60480 through 60484), we finalized a policy to redefine policy packaged drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents, as a result of the policy discussed in sections V.A.4. and V.B.2.d. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477 and 60495 through 60499, respectively) that treats nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) with newly approved pass-through status beginning in CY 2010 or later as devices, rather than drugs. To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPPS payment amount, we multiply the policy packaged drug offset fraction by the APC payment amount for the nuclear medicine procedure with which the pass-through diagnostic radiopharmaceutical is used and, accordingly, reduce the separate OPPS payment for the pass-through diagnostic radiopharmaceutical by this amount.

Beginning in CY 2011 and as discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71934 through 71936), we finalized a policy to require hospitals to append modifier ''FB'' to specified nuclear medicine procedures and to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is received without cost or with full credit. Beginning in CY 2014, we are proposing to no longer require hospitals to append modifier ''FB'' to specified nuclear medicine procedures or to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is received at no cost/full credit. Under this proposed policy, the OPPS payment amount for nuclear medicine procedures would not be reduced when a diagnostic radiopharmaceutical is received at no cost or full credit. Based on claims data, it appears that hospitals rarely receive diagnostic radiopharmaceuticals at no cost or full credit and, therefore, we do not believe that the burden on hospitals of adhering to the nuclear medicine ''FB'' modifier policy continues to be warranted.

For CY 2013, we finalized a policy to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described above. For CY 2014, we are proposing to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

Table 21 below displays the proposed APCs to which nuclear medicine procedures would be assigned in CY 2014 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 21—PROPOSED APCS TO WHICH NUCLEAR MEDICINE PROCEDURES WOULD BE ASSIGNED FOR CY 2014

Proposed CY 2014 APC	Proposed CY 2014 APC title
0308	Positron Emission Tomography (PET) Imaging.
0377	Level II Cardiac Imaging.
0378	Level II Pulmonary Imaging.
0389	Level I Non-imaging Nuclear Medicine.
0390	Level I Endocrine Imaging.
0391	Level II Endocrine Imaging.
0392	Level II Non-imaging Nuclear Medicine.
0393	Hematologic Processing & Studies.
0394	Hepatobiliary Imaging.
0395	GI Tract Imaging.
0396	Bone Imaging.
0397	Vascular Imaging.
0398	Level I Cardiac Imaging.
0400	Hematopoietic Imaging.
0401	Level I Pulmonary Imaging.
0402	Level II Nervous System Imaging.
0403	Level I Nervous System Imaging.
0404	Renal and Genitourinary Studies.
0406	Level I Tumor/Infection Imaging.
0408	Level III Tumor/Infection Imaging.
0414	Level II Tumor/Infection Imaging.

c. Proposed Payment Offset Policy for Contrast Agents

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. There currently are no contrast agents with pass-through status under the OPPS. As described in section V.A.3. of this proposed rule, we are proposing that new pass-through contrast agents would be paid at ASP+6 percent, while those new pass-through contrast agents without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

Although there are currently no contrast agents with pass-through status, we believe that a payment offset is necessary in the event that a new contrast agent is approved for pass-through status during CY 2014 in order to provide an appropriate transitional pass-through payment for new contrast agents because all of these items are packaged when they do not have pass-through status. In accordance with our standard offset methodology, we are proposing for CY 2014 to deduct from the payment for new pass-through contrast agents that are approved for pass-through status as a drug or biological during CY 2014, an amount that reflects the portion of the APC payment associated with predecessor contrast agents, in order to ensure no duplicate contrast agent payment is made.

In CY 2010, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor contrast agents when considering new contrast agents for pass-through payment (74 FR 60482 through 60484). For CY 2014, as we did in CY 2013, we are proposing to continue to apply this same policy to contrast agents. Specifically, we are proposing to utilize the policy packaged drug offset fraction for procedural APCs, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy packaged drugs divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through contrast agents that takes into consideration the otherwise applicable OPPS payment amount, we are proposing to multiply the policy packaged drug offset fraction by the APC payment amount for the procedure with which the pass-through contrast agent is used and, accordingly, reduce the separate OPPS payment for the pass-through contrast agent by this amount. We are proposing to continue to apply this methodology for CY 2014 to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 22 of this proposed rule, a specific offset based on the procedural APC would be applied to the payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

Proposed procedural APCs for which we expect a contrast offset could be applicable in the case of a pass-through contrast agent have been identified as any procedural APC with a policy packaged drug amount greater than $20 that is not a nuclear medicine APC identified in Table 21 above, and these APCs are displayed in Table 22 below. The methodology used to determine a proposed threshold cost for application of a contrast agent offset policy is described in detail in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60483 through 60484). For CY 2014, we are proposing to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 22, a specific offset based on the procedural APC would be applied to the payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

TABLE 22—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2014

Proposed CY 2014 APC	Proposed CY 2014 APC title
0080	Diagnostic Cardiac Catheterization.
0082	Coronary or Non-Coronary Atherectomy.
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization.
0093	Vascular Reconstruction/Fistula Repair without Device.
0104	Transcathether Placement of Intracoronary Stents.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0177	Level I Echocardiogram With Contrast.
0178	Level II Echocardiogram With Contrast.
0229	Level II Endovascular Revascularization of the Lower Extremity.
0278	Diagnostic Urography.
0279	Level II Angiography and Venography.
0280	Level III Angiography and Venography.
0283	Computed Tomography with Contrast.
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
0333	Computed Tomography without Contrast followed by Contrast.
0334	Combined Abdomen and Pelvis CT with Contrast.
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast.

TABLE 22—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2014—Continued

Proposed CY 2014 APC	Proposed CY 2014 APC title
0375	Ancillary Outpatient Services When Patient Expires.
0383	Cardiac Computed Tomographic Imaging.
0388	Discography.
0442	Dosimetric Drug Administration.
0653	Vascular Reconstruction/Fistula Repair with Device.
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0662	CT Angiography.
0668	Level I Angiography and Venography.
8006	CT and CTA with Contrast Composite.
8008	MRI and MRA with Contrast Composite.

d. Proposed Payment Offset Policy for Products Packaged According to the Proposed Policy to Package Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure and Drugs and Biologicals That Function as Supplies or Devices When Used in a Surgical Procedure

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. As discussed in section II.A.3. of this proposed rule, as a part of our proposed policy to package drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure, we are specifically proposing that skin substitutes and stress agents used in myocardial perfusion imaging (MPI) be policy packaged in CY 2014, in addition to diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs. We believe that a payment offset, similar to the offset currently in place for pass-through devices, diagnostic radiopharmaceuticals, and contrast agents, is necessary in order to provide an appropriate transitional pass-through payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure because all of these are packaged, or proposed to be packaged, when they do not have pass-through status. In accordance with our standard offset methodology, we are proposing for CY 2014 to deduct from the payment for pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure an amount that reflects the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made.

In CY 2009, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals when considering a new diagnostic radiopharmaceutical for pass-through payment (73 FR 68638 through 68641). For CY 2014, we are proposing to apply this same policy to drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure. Specifically, in the case of pass-through skin substitutes, we are proposing to utilize the policy packaged drug offset fraction for skin substitute procedural APCs, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy packaged drugs divided by the cost from single procedure claims in the APC. Because policy packaged radiopharmaceuticals also would be included in the drug offset fraction for the APC to which MPI procedures are assigned, in the case of pass-through stress agents, we are proposing to utilize the policy packaged drug offset fraction for the procedural APC, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy packaged drugs excluding policy packaged diagnostic radiopharmaceuticals divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through skin substitutes and pass-through stress agents that takes into consideration the otherwise applicable OPPS payment amount, we are proposing to multiply the policy-packaged drug offset fraction by the APC payment amount for the procedure with which the pass-through skin substitute or pass-through stress agent is used and, accordingly, reduce the separate OPPS payment for the pass-through skin substitute or pass-through stress agent by this amount.

Table 23 below displays the proposed APCs to which skin substitute procedures would be assigned in CY 2014 and for which we expect that an APC offset could be applicable in the case of skin substitutes with pass-through status.

Table 24 below displays the proposed APC to which MPI procedures would be assigned in CY 2014 and for which we expect that an APC offset could be applicable in the case of a stress agent with pass-through status.

We are proposing to continue to post annually on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

TABLE 23—PROPOSED APCS TO WHICH SKIN SUBSTITUTE PROCEDURES WOULD BE ASSIGNED FOR CY 2014

Proposed CY 2014 APC	Proposed CY 2014 APC title
0135	Level III Skin Repair.
0136	Level IV Skin Repair.

TABLE 24—PROPOSED APCS TO WHICH MPI PROCEDURES WOULD BE ASSIGNED FOR CY 2014

Proposed CY 2014 APC	Proposed CY 2014 APC title
0100	Cardiac Stress Tests.
0377	Level II Cardiac Imaging.

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

1. Background

Under the CY 2013 OPPS, we currently pay for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status in one of two ways: As a packaged payment included in the payment for the associated service, or as a separate payment (individual APCs). We explained in the April 7, 2000 OPPS final rule with comment period (65 FR 18450) that we generally package the cost of drugs and radiopharmaceuticals into the APC payment rate for the procedure or treatment with which the products are usually furnished. Hospitals do not receive separate payment for packaged items and supplies, and hospitals may not bill beneficiaries separately for any packaged items and supplies whose costs are recognized and paid within the national OPPS payment rate for the associated procedure or service. (Transmittal A–01–133, issued on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services.)

Packaging costs into a single aggregate payment for a service, procedure, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility.

2. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Background

As indicated in section V.B.1. of this proposed rule, in accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $60 for CYs 2008 and 2009. For CY 2010, we set the packaging threshold at $65; for CY 2011, we set the packaging threshold at $70; for CY 2012, we set the packaging threshold at $75; and for CY 2013, we set the packaging threshold at $80.

Following the CY 2007 methodology, for this CY 2014 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2014 and rounded the resulting dollar amount ($87.70) to the nearest $5 increment, which yielded a figure of $90. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT). (We note that we are not proposing a change to the PPI that is used to calculate the threshold for CY 2014; rather, this change in terminology reflects a change to the BLS naming convention for this series.) We refer below to this series generally as the PPI for Prescription Drugs.

We chose the PPI for Prescription Drugs as it reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. In addition, we chose this price series because it is publicly available and regularly published, improving public access and transparency. Forecasts of the PPI for Prescription Drugs are developed by IHS Global Insight, Inc., a nationally recognized economic and financial forecasting firm. As actual inflation for past quarters replaced forecasted amounts, the PPI estimates for prior quarters have been revised (compared with those used in the CY 2007 OPPS/ASC final rule with comment period) and have been incorporated into our calculation. Based on the calculations described above, we are proposing a packaging threshold for CY 2014 of $90. (For a more detailed discussion of the OPPS drug packaging threshold and the use of the PPI for Prescription Drugs, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086).)

b. Proposed Cost Threshold for Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals (''Threshold-Packaged Drugs'')

To determine the proposed CY 2014 packaging status for all nonpass-through drugs and biologicals that are not policy packaged for this proposed rule, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2012 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2012 claims processed before January 1, 2013 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.2.c. of this proposed rule, or for diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, and implantable biologicals that we are proposing to continue to package in CY 2014, or for the new categories of policy-packaged products proposed for CY 2014, as discussed in section II.A.3. of this proposed rule.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2014, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 70 FR 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we are proposing for separately

payable drugs and biologicals for CY 2014, as discussed in more detail in section V.B.3.b. of this proposed rule) to calculate the CY 2014 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2012 (data that were used for payment purposes in the physician's office setting, effective April 1, 2013) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2014, we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2012 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) because these are the most recent data available for use at the time of development of this proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2013. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2012 hospital claims data to determine their per day cost.

We are proposing to package items with a per day cost less than or equal to $90, and identify items with a per day cost greater than $90 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2012 HCPCS codes that were reported to the CY 2013 HCPCS codes that we display in Addendum B of this proposed rule (which is available via the Internet on the CMS Web site) for payment in CY 2014.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period will be subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in the CY 2014 OPPS/ASC final rule with comment period, we are proposing to use ASP data from the first quarter of CY 2013, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2013, along with updated hospital claims data from CY 2012. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for the CY 2014 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B to the final rule with comment period will be based on ASP data from the second quarter of CY 2013. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2013. These physician's office payment rates would then be updated in the January 2014 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2014. For items that do not currently have an ASP-based payment rate, we are proposing to recalculate their mean unit cost from all of the CY 2012 claims data and updated cost report information available for the CY 2014 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this CY 2014 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the CY 2014 OPPS/ASC final rule with comment period. Under such circumstances, we are proposing to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2014 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2013. Specifically, for CY 2014, consistent with our historical practice, we are proposing to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2013 and that are proposed for separate payment in CY 2014, and that then have per day costs equal to or less than the CY 2014 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2014 final rule, would continue to receive separate payment in CY 2014.
- HCPCS codes for drugs and biologicals that were packaged in CY 2013 and that are proposed for separate payment in CY 2014, and that then have per day costs equal to or less than the CY 2014 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2014 final rule, would remain packaged in CY 2014.
- HCPCS codes for drugs and biologicals for which we are proposing packaged payment in CY 2014 but then have per day costs greater than the CY 2014 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2014 final rule, would receive separate payment in CY 2014.

c. Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66776), we began recognizing, for OPPS payment purposes, multiple HCPCS codes reporting different dosages for the same covered Part B drugs or biologicals in order to reduce hospitals' administrative burden by permitting them to report all HCPCS codes for drugs and biologicals. In general, prior to CY 2008, the OPPS recognized for payment only the HCPCS code that described the lowest dosage of a drug or biological. We extended this recognition to multiple HCPCS codes for several other drugs under the CY 2009 OPPS (73 FR 68665). During CYs 2008 and 2009, we applied a policy that assigned the status indicator of the previously recognized HCPCS code to the associated newly recognized code(s), reflecting the packaged or separately payable status of the new code(s). In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66775), we explained that once claims data were available for these previously unrecognized HCPCS codes, we would determine the packaging status and resulting status indicator for each HCPCS code according to the general, established HCPCS code-specific methodology for determining a code's packaging status for a given update year. However, we also stated that we planned to closely follow our claims data to ensure that our annual packaging determinations for the different HCPCS codes describing the same drug or biological did not create inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490

through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages. We analyzed CY 2008 claims data for the HCPCS codes describing different dosages of the same drug or biological that were newly recognized in CY 2008 and found that our claims data would result in several different packaging determinations for different codes describing the same drug or biological. Furthermore, we found that our claims data included few units and days for a number of newly recognized HCPCS codes, resulting in our concern that these data reflected claims from only a small number of hospitals, even though the drug or biological itself may be reported by many other hospitals under the most common HCPCS code. Based on these findings from our first available claims data for the newly recognized HCPCS codes, we believed that adopting our standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes instead of others, particularly because we do not currently require hospitals to report all drug and biological HCPCS codes under the OPPS in consideration of our previous policy that generally recognized only the lowest dosage HCPCS code for a drug or biological for OPPS payment.

For CY 2014, we continue to believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes for drugs instead of others. Making packaging determinations on a drug-specific basis eliminates these incentives and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we are proposing to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2014.

For CY 2014, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2012 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. We then multiplied the weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to $90 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than $90 (so that all HCPCS codes for the same drug or biological would be separately payable). The following drugs did not have pricing information available for the ASP methodology for this CY 2014 OPPS/ASC proposed rule and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the fourth quarter CY 2012 claims data to make the packaging determinations for these drugs: HCPCS codes J3471 (Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)); J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); Q0171 (Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); Q0172 (Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); Q0175 (Perphenazine, 4 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); Q0176 (Perphenazine, 8 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); Q0177 (Hydroxyzine pamoate, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); and Q0178 (Hydroxyzine pamoate, 50 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply is displayed in Table 25 below.

TABLE 25—PROPOSED HCPCS CODES TO WHICH THE CY 2014 DRUG–SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

Proposed CY 2014 HCPCS code	Proposed CY 2014 long descriptor	Proposed CY 2014 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1440	Injection, filgrastim (g-csf), 300 mcg	K
J1441	Injection, filgrastim (g-csf), 480 mcg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	N
J1560	Injection, gamma globulin, intramuscular over 10 cc	N
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N

TABLE 25—PROPOSED HCPCS CODES TO WHICH THE CY 2014 DRUG–SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY—Continued

Proposed CY 2014 HCPCS code	Proposed CY 2014 long descriptor	Proposed CY 2014 SI
J2270	Injection, morphine sulfate, up to 10 mg	N
J2271	Injection, morphine sulfate, 100 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	K
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	K
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3120	Injection, testosterone enanthate, up to 100 mg	N
J3130	Injection, testosterone enanthate, up to 200 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7050	Infusion, normal saline solution , 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml = 1 unit)	N
J7030	Infusion, normal saline solution , 1000 cc	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	K
J8521	Capecitabine, oral, 500 mg	K
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N
Q0164	Prochlorperazine maleate, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0165	Prochlorperazine maleate, 10 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0167	Dronabinol, 2.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0168	Dronabinol, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0169	Promethazine hydrochloride, 12.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0170	Promethazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0171	Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0172	Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0175	Perphenazine, 4 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0176	Perphenazine, 8 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0177	Hydroxyzine pamoate, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0178	Hydroxyzine pamoate, 50 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N

3. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary.

Most physician Part B drugs are paid at ASP+6 percent pursuant to section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.

It has been our longstanding policy to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In this CY 2014 OPPS/ASC proposed rule, we are proposing to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

Since CY 2006, we have attempted to establish a drug payment methodology that reflects hospitals' acquisition costs for drugs and biologicals while taking into account relevant pharmacy overhead and related handling expenses. We have attempted to collect more data on hospital overhead charges for drugs and biologicals by making several proposals that would require hospitals to change the way they report the cost and charges for drugs. None of these proposals were adopted due to significant stakeholder concern, including that hospitals stated that it would be administratively burdensome to report hospital overhead charges. We established a payment policy for separately payable drugs and biologicals, authorized by section 1833(t)(14)(A)(iii)(I) of the Act, based on an ASP+X amount that is calculated by comparing the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost (70 FR 68642). We referred to this methodology as our standard drug payment methodology.

In CY 2010, taking into consideration comments made by the pharmacy stakeholders and acknowledging the limitations of the reported data due to charge compression and hospitals' reporting practices, we added an ''overhead adjustment'' (an internal adjustment of the data) by redistributing cost from coded and uncoded packaged drugs and biologicals to separately payable drugs in order to provide more appropriate payments for drugs and biologicals in the HOPD. We continued this overhead adjustment methodology through CY 2012, and further refined our overhead adjustment methodology by finalizing a policy to update the redistribution amount for inflation and to keep the redistribution ratio constant between the proposed rule and the final rule. For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385).

We noted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386) that application of the standard drug payment methodology, with the overhead adjustment, has always yielded a finalized payment rate in the range of ASP+4 percent to ASP+6 percent for nonpass-through separately payable drugs. We stated that the historic ASP+4 to ASP+6 percentage range is an appropriate payment rate for separately payable drugs and biologicals administered within the HOPD, including acquisition and pharmacy overhead and related expenses. However, because of continuing uncertainty about the full cost of pharmacy overhead and acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs, we indicated our concern that the continued use of the standard drug payment methodology (including the overhead adjustment) still may not appropriately account for average acquisition and pharmacy overhead cost and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate as they could be.

In that final rule with comment period, we discussed that section 1833(t)(14)(A)(iii)(II) of the Act requires an alternative methodology for determining payment rates for SCODs wherein, if hospital acquisition cost data are not available, payment shall be equal (subject to any adjustment for overhead costs) to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386), we noted that section 1833(t)(14)(A)(iii)(II) of the Act authorizes the Secretary to calculate and adjust, as necessary, the average price for a drug in the year established under section 1842(o), 1847A, or 1847B of the Act, as the case may be, in determining payment for SCODs. Pursuant to sections 1842(o) and 1847A of the Act, Part B drugs are paid at ASP+6 percent when furnished in physicians' offices. We indicated that we believe that establishing the payment rates based on the statutory default of ASP+6 percent is appropriate as it yields increased predictability in payment for separately payable drugs and biologicals under the OPPS. We also noted that ASP+6 percent is an appropriate payment amount because it is consistent with payment amounts yielded by our drug payment methodologies over the past 7 years. Therefore, considering stakeholder and provider feedback, continued limitations of the hospital claims and cost data on drugs and biologicals, and Panel recommendations, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68389), we finalized our proposal for CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act, referred to as the statutory default. We also finalized our proposal that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment, and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals and that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biological for CY 2013 (77 FR 68389).

b. Proposed CY 2014 Payment Policy

For CY 2014, we are proposing to continue our CY 2013 policy and pay

for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act, referred to as the statutory default. We are proposing that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment, and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. We also are proposing that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals.

4. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in CY 2010 and continuing for CY 2013, we established a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through separately payable therapeutic radiopharmaceuticals in CY 2014. Therefore, we are proposing for CY 2014 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also are proposing to rely on CY 2012 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals, according to our usual process for updating the payment rates for separately payable drugs and biologicals, on a quarterly basis if updated ASP information is available. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

The proposed CY 2014 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

5. Proposed Payment for Blood Clotting Factors

For CY 2013, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee. That is, for CY 2013, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2013 updated furnishing fee was $0.188 per unit.

For CY 2014, we are proposing to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician office and inpatient hospital setting, and first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we are proposing to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

6. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) did not address the OPPS payment in CY 2005 and subsequent years for drugs, biologicals, and radiopharmaceuticals that have assigned HCPCS codes, but that do not have a reference AWP or approval for payment as pass-through drugs or biologicals. Because there was no statutory provision that dictated payment for such drugs, biologicals, and radiopharmaceuticals in CY 2005, and because we had no hospital claims data to use in establishing a payment rate for them, we investigated several payment options for CY 2005 and discussed them in detail in the CY 2005 OPPS final rule with comment period (69 FR 65797 through 65799).

For CYs 2005 to 2007, we implemented a policy to provide separate payment for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes (specifically those new drug, biological, and radiopharmaceutical HCPCS codes in each of those calendar years that did not crosswalk to predecessor HCPCS codes) but which did not have pass-through status, at a rate that was equivalent to the payment they received in the physician's office setting, established in accordance with the ASP methodology for drugs and biologicals, and based on charges adjusted to cost for radiopharmaceuticals. For CYs 2008 and 2009, we finalized a policy to provide payment for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals) and biologicals (excluding implantable biologicals for CY 2009) with HCPCS codes, but which did not have pass-through status and were without OPPS hospital claims data, at ASP+5 percent and ASP+4 percent, respectively, consistent with the final OPPS payment methodology for other separately payable drugs and biologicals. New therapeutic radiopharmaceuticals were paid at charges adjusted to cost based on the statutory requirement for CY 2008 and CY 2009 and payment for new diagnostic radiopharmaceuticals was packaged in both years.

For CY 2010, we continued to provide payment for new drugs (excluding contrast agents) and biologicals with

HCPCS codes that do not have pass-through status and are without OPPS hospital claims data at ASP+4 percent, consistent with the CY 2010 payment methodology for other separately payable nonpass-through drugs and biologicals. We also finalized a policy to extend the CY 2009 payment methodology to new therapeutic radiopharmaceutical HCPCS codes, consistent with our final policy in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60581 through 60526), providing separate payment for therapeutic radiopharmaceuticals that do not crosswalk to CY 2009 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data at ASP+4 percent. This policy was continued in CYs 2011, 2012, and 2013, paying for new drugs, biologicals, and radiopharmaceuticals that do not have pass-through status, and are without OPPS hospital claims data at ASP+5 percent, ASP+4 percent, and ASP+6 percent, respectively, consistent with the final OPPS payment methodology for other separately payable drugs and biological during those payment years.

For CY 2014, we are proposing to provide payment for new drugs, biologicals, and therapeutic radiopharmaceuticals that do not have pass-through status at ASP+6 percent, consistent with the proposed CY 2014 payment methodology for other separately payable nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals to pay at ASP+6 percent based on the statutory default. We believe this proposed policy would ensure that new nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals would be treated like other drugs, biologicals, and therapeutic radiopharmaceuticals under the OPPS.

For CY 2014, we also are proposing to package payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure, with HCPCS codes but without claims data (those new CY 2014 HCPCS codes that do not crosswalk to predecessor HCPCS codes). This is consistent with the proposed policy packaging all existing nonpass-through diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure, as discussed in more detail in section II.A.3. of this proposed rule.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2014, we are proposing to continue the policy we implemented beginning in CY 2005 of using the WAC for the product to establish the initial payment rate for new nonpass-through drugs and biologicals with HCPCS codes, but which are without OPPS claims data and are not diagnostic radiopharmaceuticals and contrast agents. However, we noted that if the WAC is also unavailable, we would make payment at 95 percent of the product's most recent AWP. We also are proposing to assign status indicator ''K'' (for separately paid nonpass-through drugs and biologicals, including therapeutic radiopharmaceuticals) to HCPCS codes for new drugs and biologicals without OPPS claims data and for which we have not granted pass-through status. With respect to new, nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals for which we do not have ASP data, we are proposing that once their ASP data become available in later quarterly submissions, their payment rates under the OPPS would be adjusted so that the rates would be based on the ASP methodology and set to the finalized ASP-based amount (proposed for CY 2014 at ASP+6 percent) for items that have not been granted pass-through status. This proposed policy, which utilizes the ASP methodology that requires us to use WAC data when ASP data are unavailable and 95 percent of AWP when WAC and ASP data are unavailable, for new nonpass-through drugs and biologicals with an ASP, is consistent with prior years' policies for these items, and would ensure that new nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, biologicals, and therapeutic radiopharmaceuticals under the OPPS, unless they are granted pass-through status.

Similarly, we are proposing to continue to base the initial payment for new therapeutic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs are also unavailable, we are proposing to make payment for new therapeutic radiopharmaceuticals at 95 percent of the products' most recent AWP because we would not have mean costs from hospital claims data upon which to base payment. As we are proposing with new drugs and biologicals, we are proposing to continue our policy of assigning status indicator ''K'' to HCPCS codes for new therapeutic radiopharmaceuticals without OPPS claims data for which we have not granted pass-through status.

Consistent with other ASP-based payment, for CY 2014 we are proposing to announce any changes to the payment amounts for new drugs and biologicals in the CY 2014 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2014 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are necessary. The payment rates for new therapeutic radiopharmaceuticals also would be changed accordingly based on later quarter ASP submissions. We note that the new CY 2014 HCPCS codes for drugs, biologicals and therapeutic radiopharmaceuticals are not available at the time of development of this proposed rule. However, these agents will be included in Addendum B to the CY 2014 OPPS/ASC final rule with comment period (which will be available via the Internet on the CMS Web site), where they will be assigned comment indicator ''NI.'' This comment indicator reflects that their interim final OPPS treatment is open to public comment in the CY 2014 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2012 and/or CY 2013 for which we did not have CY 2012 hospital claims data available for this proposed rule and for which there are no other HCPCS codes that describe different doses of the same drug, but which have pricing information available for the ASP methodology. We note that there are currently no therapeutic radiopharmaceuticals in this category. In order to determine the packaging status of these products for CY 2014, we calculated an estimate of the per day cost of each of these items by multiplying the payment rate of each product based on ASP+6 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting. This rationale was first adopted in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68666 and 68667).

We are proposing to package items for which we estimated the per day administration cost to be less than or equal to $90, which is the general

packaging threshold that we are proposing for drugs, biologicals, and therapeutic radiopharmaceuticals in CY 2014. We are proposing to pay separately for items with an estimated per day cost greater than $90 (with the exception of diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure, which we are proposing to package regardless of cost, as discussed in more detail in section II.A.3. of this proposed rule) in CY 2014. We are proposing that the CY 2014 payment for separately payable items without CY 2012 claims data would be ASP+6 percent, similar to payment for other separately payable nonpass-through drugs and biologicals under the OPPS. In accordance with the ASP methodology paid in the physician's office setting, in the absence of ASP data, we are proposing to use the WAC for the product to establish the initial payment rate. However, we note that if the WAC is also unavailable, we would make payment at 95 percent of the most recent AWP available.

The proposed estimated units per day and status indicators for these items are displayed in Table 26 below.

TABLE 26—DRUGS AND BIOLOGICALS WITHOUT CY 2012 CLAIMS DATA

CY 2014 HCPCS code	CY 2014 Long descriptor	Estimated average number of units per day	Proposed CY 2014 SI	Proposed CY 2014 APC
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	K	1422
J0205	Injection, alglucerase, per 10 units	420	K	0900
J0215	Injection, alefacept, 0. 5 mg	29	K	1633
J0220	Injection, alglucosidase alfa, 10 mg, not otherwise specified	150	K	9234
J0364	Injection, apomorphine hydrochloride, 1 mg	1	N	N/A
J0395	Injection, arbutamine hcl, 1 mg	20	K	1432
J0725	Injection, chorionic gonadotropin, per 1,000 usp units	1	N	N/A
J1324	Injection, enfuvirtide, 1 mg	216	K	1361
J1435	Injection, estrone, per 1 mg	150	K	1435
J1620	Injection, gonadorelin hydrochloride, per 100 mcg	11	N	N/A
J1730	Injection, diazoxide, up to 300 mg	1	N	N/A
J1835	Injection, itraconazole, 50 mg	80	N	N/A
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	1540	K	1139
J2725	Injection, protirelin, per 250 mcg	4	K	1357
J3355	Injection, urofollitropin, 75 iu	2	K	1741
J7196	Injection, antithrombin recombinant, 50 i. U.	268	K	1332
J7513	Daclizumab, parenteral, 25 mg	2	K	1612
J8562	Fludarabine phosphate, oral, 10 mg	1	N	N/A
J8650	Nabilone, oral, 1 mg	4	K	1424
J9216	Injection, interferon, gamma 1–b, 3 million units	1	K	0838
J9226	Histrelin implant (supprelin la), 50 mg	1	K	1142
J9300	Injection, gemtuzumab ozogamicin, 5 mg	1	K	9004
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050

Finally, there were 11 drugs and biologicals, shown in Table 27, that were payable in CY 2012 but for which we lacked CY 2012 claims data and any other pricing information for the ASP methodology for this CY 2014 OPPS/ASC proposed rule. In CY 2009, for similar items without CY 2007 claims data and without pricing information for the ASP methodology, we stated that we were unable to determine their per day cost and we packaged these items for the year, assigning these items status indicator ''N.''

For CY 2010, we finalized a policy to change the status indicator for drugs and biologicals previously assigned a payable status indicator to status indicator ''E'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) whenever we lacked claims data and pricing information and were unable to determine the per day cost. In addition, we noted that we would provide separate payment for these drugs and biologicals if pricing information reflecting recent sales became available mid-year in CY 2010 for the ASP methodology. If pricing information became available, we would assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2010. We continued this policy for CYs 2011, 2012, and 2013 (75 FR 71973, 76 FR 74334, and 77 FR 68396, respectively).

For CY 2014, we are proposing to continue to assign status indicator ''E'' to drugs and biologicals that lack CY 2012 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2012 hospital claims data and data based on the ASP methodology that are assigned status indicator ''E'' on this basis at the time of this proposed rule for CY 2014 are displayed in Table 27 below. If pricing information becomes available, we are proposing to assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2014.

TABLE 27—DRUGS AND BIOLOGICALS WITHOUT CY 2012 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2014 HCPCS code	CY 2014 Long descriptor	Proposed CY 2014 SI
90393	Vaccina immune globulin, human, for intramuscular use	E
90644	Meningococcal conjugate vaccine, serogroups c & y and hemophilus influenza b vaccine (hib-mency), 4 dose schedule, when administered to children 2–15 months of age, for intramuscular use.	E
90727	Plague vaccine, for intramuscular use	E
J0190	Injection, biperiden lactate, per 5 mg	E
J0350	Injection, anistreplase, per 30 units	E
J1180	Injection, dyphylline, up to 500 mg	E
J2460	Injection, oxytetracycline hcl, up to 50 mg	E
J2940	Injection, somatrem, 1 mg	E
J7191	Factor viii (antihemophilic factor (porcine)), per i. U.	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9215	Injection, interferon, alfa-n3, (human leukocyte derived), 250,000 iu	E

C. Nuclear Medicine Procedure-to-Radiolabeled Product Edits

Beginning January 1, 2008, CMS implemented OPPS edits that require hospitals to include a HCPCS code for a radiolabeled product when a separately payable nuclear medicine procedure is present on a claim. For CY 2014, we are proposing to no longer require the nuclear medicine procedure-to-radiolabeled product edits. Under this proposal, hospitals would still be expected to adhere to the guidelines of correct coding and append the correct radiolabeled product code to the claim when applicable. However, claims would no longer be returned to providers when HCPCS codes for radiolabeled products do not appear on claims with nuclear medicine procedures. We believe that this is appropriate because hospitals have now had several years of experience reporting procedures involving radiolabeled products and have grown accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. Therefore, we do not believe that the burden on hospitals of adhering to the nuclear medicine procedure-to-radiolabeled product edits continues to be warranted. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2014 entails estimating spending for two groups of items. The first group of items consists of device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2014. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2013 or beginning in CY 2014. The sum of the CY 2014 pass-through estimates for these two groups of device categories would equal the total CY 2014 pass-through spending estimate for device categories with pass-through status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2013 OPPS/ASC final rule with comment period (77 FR 68397). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) is the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), we include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. We note that the Part B drug CAP program has been postponed since CY 2009, and such a program has

not been proposed to be reinstated for CY 2014. Because we are proposing to pay for most nonpass-through separately payable drugs and biologicals under the CY 2014 OPPS at ASP+6 percent, as we discussed in section V.B.3. of this proposed rule, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because we are proposing to pay for CY 2014 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this proposed rule, our estimate of drug and biological pass-through payment for CY 2014 for this group of items is $0, as discussed below.

Payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents, without pass-through status will always be packaged into payment for the associated procedures and these products would not be separately paid. In addition, we are proposing to policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure for CY 2014, as discussed in section II.A.3. of this proposed rule. All of these policy-packaged drugs and biologicals with pass-through status would be paid at ASP+6 percent like other pass-through drugs and biologicals for CY 2014. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through status approved prior to CY 2014 is not $0. In section V.A.4. of this proposed rule, we discuss our proposed policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we are proposing to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we are proposing to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that would continue to be eligible for pass-through payment in CY 2014. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2013 or beginning in CY 2014. The sum of the proposed CY 2014 pass-through estimates for these two groups of drugs and biologicals equals the proposed total CY 2014 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Proposed Estimate of Pass-Through Spending

We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2014, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004 through CY 2013 (77 FR 68398).

For the first group of devices for pass-through payment estimation purposes, there currently are no device categories receiving pass-through payment in CY 2013 that would continue to be eligible for pass-through payment for CY 2014. As discussed in section IV.A. of this proposed rule, we finalized in the CY 2013 OPPS/ASC final rule with comment period the expiration of pass-through payment for three device categories after the end of CY 2013. Therefore, we estimate that CY 2014 pass-through expenditures for the first group of pass-through device categories to be $0. In estimating our CY 2014 pass-through spending for device categories in the second group, we include: Device categories that we knew at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2014 (of which there are none); additional device categories that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2014; and contingent projections for new device categories established in the second through fourth quarters of CY 2014. We are proposing to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the estimate of CY 2014 pass-through spending for this second group of device categories is $10 million. Using our established methodology, we are proposing that the total estimated pass-through spending for device categories for CY 2014 (spending for the first group of device categories ($0) plus spending for the second group of device categories ($10 million)) would be $10 million.

To estimate CY 2014 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through status for CY 2014, we are proposing to utilize the most recent Medicare physician's office data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2014 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals. contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure) that will be continuing on pass-through status in CY 2014, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for policy-packaged drugs and biologicals is proposed to be packaged if the product was not paid separately due to its pass-through status, we are proposing to include in the CY 2014 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determined that the policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment. For this proposed rule, using the proposed methodology described above, we calculated a CY 2014 proposed spending estimate for this first group of drugs and biologicals of approximately $0.962 million.

To estimate proposed CY 2014 pass-through spending for drugs and biologicals in the second group (that is,

drugs and biologicals that we knew at the time of development of the proposed rule are newly eligible for pass-through payment in CY 2014, additional drugs and biologicals that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2014, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2014), we are proposing to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2014 pass-through payment estimate. We also are proposing to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2014 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $0.165 million.

As discussed in section V.A. of this proposed rule, radiopharmaceuticals are considered drugs for pass-through purposes. Therefore, we include radiopharmaceuticals in our proposed CY 2014 pass-through spending estimate for drugs and biologicals. Our proposed CY 2014 estimate for total pass-through spending for drugs and biologicals (spending for the first group of drugs and biologicals ($0.962 million) plus spending for the second group of drugs and biologicals ($0.165 million)) equals $1.127 million.

In summary, in accordance with the methodology described above in this section, for this proposed rule, we estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2014 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2014 would be approximately $11 million (approximately $10 million for device categories and approximately $1 million for drugs and biologicals), which represents 0.02 percent of total projected OPPS payments for CY 2014. We estimate that pass-through spending in CY 2014 would not amount to 2.0 percent of total projected OPPS CY 2014 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits

A. Background

Currently, hospitals report HCPCS visit codes to describe three types of OPPS services: clinic visits, emergency department (ED) visits, and critical care services, including trauma team activation. Historically, we have recognized the CPT and HCPCS codes describing clinic visits, Type A and Type B (ED) visits, and critical care services, which are listed below in Table 28. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74338 through 74346) for a full discussion of our policy on OPPS payment for hospital outpatient visits for CY 2013 and prior years.

TABLE 28—HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES

CY 2013 HCPCS code	CY 2013 descriptor
Clinic Visit HCPCS Codes	
99201	Office or other outpatient visit for the evaluation and management of a new patient (Level 1).
99202	Office or other outpatient visit for the evaluation and management of a new patient (Level 2).
99203	Office or other outpatient visit for the evaluation and management of a new patient (Level 3).
99204	Office or other outpatient visit for the evaluation and management of a new patient (Level 4).
99205	Office or other outpatient visit for the evaluation and management of a new patient (Level 5).
99211	Office or other outpatient visit for the evaluation and management of an established patient (Level 1).
99212	Office or other outpatient visit for the evaluation and management of an established patient (Level 2).
99213	Office or other outpatient visit for the evaluation and management of an established patient (Level 3).
99214	Office or other outpatient visit for the evaluation and management of an established patient (Level 4).
99215	Office or other outpatient visit for the evaluation and management of an established patient (Level 5).
Emergency Department Visit HCPCS Codes	
99281	Emergency department visit for the evaluation and management of a patient (Level 1).
99282	Emergency department visit for the evaluation and management of a patient (Level 2).
99283	Emergency department visit for the evaluation and management of a patient (Level 3).
99284	Emergency department visit for the evaluation and management of a patient (Level 4).
99285	Emergency department visit for the evaluation and management of a patient (Level 5).
G0380	Type B emergency department visit (Level 1).
G0381	Type B emergency department visit (Level 2).
G0382	Type B emergency department visit (Level 3).
G0383	Type B emergency department visit (Level 4).
G0384	Type B emergency department visit (Level 5).
Critical Care Services HCPCS Codes	
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes.
99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes.
G0390	Trauma response associated with hospital critical care service.

B. Proposed Payment for Hospital Outpatient Clinic and Emergency Department Visits

Since April 7, 2000, we have instructed hospitals to report facility resources for clinic and ED hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level (65 FR 18451). Because a national set of hospital-specific codes and guidelines do not currently exist, we have advised hospitals that each hospital's internal guidelines that determine the levels of clinic and ED visits to be reported should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

While many hospitals have advocated for hospital-specific national guidelines for visit billing since the OPPS started in 2000, and we have signaled through rulemaking our intent to develop guidelines, this complex undertaking has proven challenging. Our work with interested stakeholders, such as hospital associations, along with a contractor, has confirmed that no single approach could consistently and accurately capture hospitals' relative costs. Public comments received on this issue, as well as our own knowledge of how clinics operate, have led us to conclude that it is not feasible to adopt a set of national guidelines for reporting hospital clinic visits that can accommodate the enormous variety of patient populations and service-mix provided by hospitals of all types and sizes throughout the country. Moreover, no single approach appears to be broadly endorsed by the stakeholder community.

For CY 2014, we are proposing to modify our longstanding policies related to hospital outpatient clinic and ED visits. Rather than recognizing five levels of clinic and ED visits respectively, we are proposing to create three new alphanumeric Level II HCPCS codes to describe all levels of each type of clinic and ED visit, as discussed in greater detail below. We believe a policy that recognizes a single visit level for clinic visits, Type A ED visits, and Type B ED visits for payment under the OPPS is appropriate for several reasons. First, the proposal is in line with our strategic goal of using larger payment bundles to maximize hospitals' incentives to provide care in the most efficient matter as stated in section II.A.3. of this proposed rule. We believe this proposal will remove any incentives hospitals may have to provide medically unnecessary services or expend additional, unnecessary resources to achieve a higher level of visit payment under the OPPS. Second, we believe that it is important to consider ways in which we can reduce the administrative burden that Medicare payment policies place on hospitals, while maintaining our ability to calculate accurate payment rates under the OPPS. We believe that replacing the 20 HCPCS codes currently recognized for clinic visits and ED visits with three new alphanumeric Level II HCPCS codes would reduce administrative burden and would be easily adopted by hospitals, because the three new codes would require hospitals to distinguish only among clinic visits, Type A ED visits, and Type B ED visits. Discontinuing the use of the five levels of HCPCS visit codes for clinic and Type A and Type B ED visits would reduce hospitals' administrative burden by eliminating the need for them to develop and apply their own internal guidelines to differentiate among five levels of resource use for every clinic visit and ED visit they provide, and by eliminating the need to distinguish between new and established patients. Third, our proposal allows a large universe of claims to be utilized for ratesetting for each of the three newly proposed alphanumeric Level II HCPCS visit codes. We believe this large volume of claims available for ratesetting for each of the newly proposed alphanumeric Level II HCPCS visit codes will allow us to capture a very broad spectrum of cases ranging from extremely low complexity cases to extremely high complexity cases. We believe this large and diverse spectrum of clinical complexity and resource variation within the claims as well as the very high volume of claims that we propose to use for ratesetting for the newly proposed alphanumeric Level II HCPCS visit new codes will allow us to have very accurate data upon which to develop accurate and appropriate payments. Lastly, we also believe that removing the differentiation among five levels of intensity for each visit will eliminate any incentive for hospitals to ''upcode'' patients whose visits do not fall clearly into one category or another.

For these reasons, for CY 2014, we are proposing to discontinue our longstanding policy of recognizing five distinct visit levels for clinic visits and ED visits based on the existing HCPCS E/M codes, and instead recognize three new alphanumeric HCPCS codes for each visit type. Specifically, we are proposing to create a new alphanumeric HCPCS code (GXXXC) for hospital use only representing any clinic visit under the OPPS and to assign the newly created alphanumeric clinic visit HCPCS code (GXXXC) to its own newly created APC 0634. Using CY 2012 claims data, we are proposing to develop CY 2014 OPPS payment rates for the new HCPCS code GXXXC based on the total mean cost of the levels one through five CPT E/M codes for clinic visits currently recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). While we would use data for CPT codes 99201 through 99205 and 99211 through 99215 from claims billed in CY 2012 to calculate the mean cost for new APC 0634, we would no longer recognize those CPT codes when they appear on hospital claims effective January 1, 2014. We also are proposing to no longer recognize a distinction between new and established patient clinic visits. Under this proposal, all clinic visits would be reported using new HCPCS code GXXXC, regardless of whether or not the patient has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit.

In addition, we are proposing to discontinue our longstanding policy of recognizing five distinct visit levels for Type A ED visits and instead are proposing to create a new alphanumeric HCPCS code (GXXXA) for hospital use only representing any Type A ED visit under the OPPS. We are proposing to assign the newly created alphanumeric Type A ED visit HCPCS code (GXXXA) to its own newly created APC 0635. Using CY 2012 claims data, we are proposing to develop CY 2014 OPPS payment rates for new HCPCS code GXXXA based on the total mean cost of the levels 1 through 5 CPT E/M codes for Type A ED visits currently recognized under the OPPS (CPT codes 99281 through 99285). While we would use data for CPT codes 99281 through 99285 from claims billed in CY 2012 to calculate the mean cost for new APC 0635, we would no longer recognize those CPT codes when they appear on hospital claims effective January 1, 2014. Similarly, we also are proposing to discontinue our longstanding policy of recognizing five distinct visit levels for Type B ED visits and instead are proposing to create a new alphanumeric HCPCS code (GXXXB) representing all Type B ED visits under the OPPS. We are proposing to assign the newly created alphanumeric Type B ED visit HCPCS code (GXXXB) to its own newly created APC 0636. Using CY 2012 claims data, we are proposing to develop CY 2014 OPPS payment rates

for new HCPCS code GXXXB based on the total mean cost of the levels 1 through 5 HCPCS codes for Type B ED visits currently recognized under the OPPS (HCPCS codes G0380 through G0384). While we would use data for HCPCS codes G0380 through G0384 from claims billed in CY 2012 to calculate the mean cost for new APC 0636, we would no longer recognize those HCPCS codes for Type B ED visits when they appear on hospital claims effective January 1, 2014.

We note that we would use the hospital claims data for new HCPCS codes GXXXA, GXXXB, and GXXXC when available for future ratesetting. The proposed changes to the visit coding and payment structure are summarized below in Table 29. We welcome public comments on our CY 2014 proposal to recognize a single visit level for clinic, Type A ED, and Type B ED visits for payment under the OPPS. We believe this proposal will allow us to make accurate payments for visits broad-scale because we will be using data from the universe of hospital outpatient visits, for which we have an extremely high volume of claims representing the entire spectrum of costs incurred by hospitals. Nonetheless, we are interested in hearing from stakeholders regarding whether a different approach may be preferable to capture the resource utilization for extremely low complexity cases as well as extremely high complexity cases or to otherwise recognize a difference among visit levels. While we do not believe, based on our current assessment, that it is necessary to provide additional payment levels or carve out these cases to make accurate and appropriate payments for visits, we are interested in hearing from hospitals whether there are certain cases that would not be best accommodated by a single level of payment. If such cases exist, we welcome stakeholder input into whether and how this proposal could be changed in the final rule to either make exceptions for or accommodate these special cases. If commenters provide compelling comments describing such special cases or the need for additional payment levels, should they exist, and if there are alternative policies that would more accurately and appropriately pay for visits, we would consider implementing a different policy in the final rule. We note that, to the extent that commenters recommend that additional levels of payment or special high complexity or low complexity cases be recognized, we also would be interested in how we should define and differentiate those levels or cases.

TABLE 29—CY 2013 CLINIC AND EMERGENCY DEPARTMENT VISIT HCPCS CODES AND APC ASSIGNMENTS COMPARED TO PROPOSED CY 2014 CLINIC AND EMERGENCY DEPARTMENT VISIT HCPCS CODES AND APC ASSIGNMENTS

Visit type	CY 2013		Proposed CY 2014	
	HCPCS code	APC	HCPCS code	APC
CLINIC VISIT	99201	0604	GXXXC	0634
	99202	0605		
	99203	0606		
	99204	0607		
	99205	0608		
	99211	0604		
	99212	0605		
	99213	0605		
	99214	0606		
	99215	0607		
TYPE A ED VISIT	99281	0609	GXXXA	0635
	99282	0613		
	99283	0614		
	99284	0615		
	99285	0616		
TYPE B ED VISIT	G0380	0626	GXXXB	0636
	G0381	0627		
	G0382	0628		
	G0383	0629		
	G0384	0630		

C. Proposed Payment for Critical Care Services

We are proposing to continue the methodology established in the CY 2011 OPPS/ASC final rule with comment period for calculating a payment rate for critical care services that includes packaged payment of ancillary services. For CY 2010 and in prior years, the AMA CPT Editorial Panel defined critical care CPT codes 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and 99292 (Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)) to include a wide range of ancillary services such as electrocardiograms, chest X-rays, and pulse oximetry. As we have stated in manual instruction, we expect hospitals to report in accordance with CPT guidance unless we instruct otherwise. For critical care in particular, we instructed hospitals that any services that the CPT Editorial Panel indicates are included in the reporting of CPT code 99291 (including those services that would otherwise be reported by and paid to hospitals using any of the CPT codes specified by the CPT Editorial Panel) should not be billed separately. Instead, hospitals were instructed to report charges for any services provided as part of the critical care services. In establishing payment rates for critical care services and other services, CMS packages the costs of certain items and services separately reported by HCPCS codes into payment for critical care services and other services, according to the standard OPPS methodology for packaging costs (Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, Section 160.1).

For CY 2011, the AMA CPT Editorial Panel revised its guidance for the critical care codes to specifically state

that, for hospital reporting purposes, critical care codes do not include the specified ancillary services. Beginning in CY 2011, hospitals that report in accordance with the CPT guidelines should report all of the ancillary services and their associated charges separately when they are provided in conjunction with critical care. Because the CY 2011 payment rate for critical care services was based on hospital claims data from CY 2009, during which time hospitals would have reported charges for any ancillary services provided as part of the critical care services, we stated in the CY 2011 OPPS/ASC final rule with comment period that we believed it was inappropriate to pay separately in CY 2011 for the ancillary services that hospitals may now report in addition to critical care services (75 FR 71988). Therefore, for CY 2011, we continued to recognize the existing CPT codes for critical care services and established a payment rate based on historical data, into which the cost of the ancillary services was intrinsically packaged. We also implemented claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment. We noted in the CY 2011 OPPS/ASC final rule with comment period that the payment status of the ancillary services would not change when they are not provided in conjunction with critical care services. We assigned status indicator ''Q3'' (Codes That May Be Paid Through a Composite APC) to the ancillary services to indicate that payment for these services is packaged into a single payment for specific combinations of services and made through a separate APC payment or packaged in all other circumstances, in accordance with the OPPS payment status indicated for status indicator ''Q3'' in Addendum D1 to the CY 2011 OPPS/ASC final rule with comment period. The ancillary services that were included in the definition of critical care prior to CY 2011 and that are conditionally packaged into the payment for critical care services when provided on the same date of service as critical care services for CY 2011 were listed in Addendum M to that final rule with comment period.

Because the CY 2012 costs for critical care services were based upon CY 2010 claims data, which reflected the CPT billing guidance that was in effect prior to CY 2011, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74343 through 74344), we continued the methodology established in the CY 2011 OPPS/ASC final rule with comment period of calculating a payment rate for critical care services based on our historical claims data, into which the cost of the ancillary services is intrinsically packaged for CY 2012. We also continued to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

As we discussed in the CY 2013 OPPS/ASC final rule with comment period, the CY 2011 hospital claims data on which the CY 2013 payment rates are based reflect the first year of claims billed under the revised CPT guidance to allow the reporting of all the ancillary services and their associated charges separately when they are provided in conjunction with critical care (77 FR 68402). Because our policy to establish relative payment weights based on geometric mean cost data for CY 2013 represented a change from our historical practice to base payment rates on median costs, and because we now have hospital claims data for the first time reflecting the revised coding guidance for critical care, we reviewed the CY 2011 hospital claims data available for the CY 2013 OPPS/ASC final rule with comment period and determined that the data showed increases in both the mean and median line item costs as well as the mean and median line item charges for CPT code 99291, when compared to CY 2010 hospital claims data. Specifically, we noted that the mean and median line item costs increased 13 percent and 16 percent, respectively, and the mean and median line item charges increased 11 percent and 14 percent, respectively. Additionally, when compared to CY 2010 hospital claims data, CY 2011 hospital claims data showed no substantial change in the ancillary services that were presented on the same claims as critical care services, and also showed continued low volumes of many ancillary services. We stated in the CY 2013 OPPS/ASC final rule with comment period that, had the majority of hospitals changed their billing practices to separately report and charge for the ancillary services formerly included in the definition of critical care CPT codes 99291 and 99292, we would have expected to see a decrease in the costs and charges for these CPT codes, and a significant increase in ancillary services reported on the same claims. We indicated that the lack of a substantial change in the services reported on critical care claims, along with the increases in the line item costs and charges for critical care services, strongly suggested that many hospitals did not change their billing practices for CPT code 99291 following the revision to the CPT coding guidance effective January 1, 2011.

In light of not having claims data to support a significant change in hospital billing practices, we stated in the CY 2013 OPPS/ASC final rule with comment period that we continued to believe that it is inappropriate to pay separately in CY 2013 for the ancillary services that hospitals may now report in addition to critical care services. Therefore, for CY 2013, we continued our CY 2011 and CY 2012 policy to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also continued to implement claims processing edits that conditionally packaged payment for the ancillary services that were reported on the same date of service as critical care services in order to avoid overpayment. We stated that we would continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to this policy are warranted based on changes in hospitals' billing practices.

When compared to CY 2011 hospital claims data used for the CY 2013 OPPS ratesetting, CY 2012 hospital claims data used for the CY 2014 OPPS ratesetting show increases in the mean line- item costs as well as the mean line-item charges for CPT code 99291, which continue to suggest that hospitals did not change their billing practices for CPT code 99291 following the revision to the CPT coding guidance effective January 1, 2011. In light of not having claims data to support a significant change in hospital billing practices, we continue to believe that it is inappropriate to pay separately in CY 2014 for the ancillary services that hospitals may now report in addition to critical care services. Therefore, for CY 2014, we are proposing to continue our CY 2011, CY 2012, and CY 2013 policy to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also are proposing to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment. We will continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to this policy are warranted based on changes in hospitals' billing practices.

VIII. Proposed Payment for Partial Hospitalization Services

A. Background

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. Section 1861(ff)(1) of the Act defines partial hospitalization services as ''the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.'' Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a partial hospitalization program (PHP) is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC) (as defined in subparagraph (B)), and ''which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting.'' Section 1861(ff)(3)(B) of the Act defines a community mental health center for purposes of this benefit.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the OPD services to be covered under the OPPS. The Medicare regulations that implement this provision specify, under 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act, in pertinent part, requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs'' using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, subparagraph (B) provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we have developed the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.''

Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs have been used to calculate the relative payment weights for PHP APCs.

From CY 2003 through CY 2006, the median per diem costs for CMHCs fluctuated significantly from year to year, while the median per diem costs for hospital-based PHPs remained relatively constant. We were concerned that CMHCs may have increased and decreased their charges in response to Medicare payment policies. Therefore, we began efforts to strengthen the PHP benefit through extensive data analysis and policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). We made two refinements to the methodology for computing the PHP median: the first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill. We refer readers to a complete discussion of these refinements in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676).

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tiered payment approach for PHP services under which we paid one amount for days with 3 services (APC 0172 Level I Partial Hospitalization) and a higher amount for days with 4 or more services (APC 0173 Level II Partial Hospitalization). We refer readers to section X.B. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68693) for a full discussion of the two-tiered payment system. In addition, for CY 2009, we finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694).

Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). These changes have helped to strengthen the PHP benefit. We also revised the partial hospitalization benefit to include several coding updates. We refer readers to section X.C.3. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68695 through 68697) for a full discussion of these requirements.

For CY 2010, we retained the two-tiered payment approach for PHP services and used only hospital-based PHP data in computing the APC per diem payment rates. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In CY 2011, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care ''other than in an individual's home or in an inpatient or residential setting.'' In addition, in accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act. We discussed our finalized policies for these two provisions of HCERA 2010 in section X.C. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71990).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we also established four separate PHP APC per diem payment rates, two for CMHCs (for Level I and Level II services) and two for hospital-based PHPs (for Level

I and Level II services), based on each provider's own unique data. As stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46300) and the final rule with comment period (75 FR 71991), for CY 2011, using CY 2009 claims data, CMHC costs had significantly decreased again. We attributed the decrease to the lower cost structure of CMHCs compared to hospital-based PHP providers, and not the impact of the CY 2009 policies. CMHCs have a lower cost structure than hospital-based PHP providers, in part, because the data showed that CMHCs generally provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. Therefore, it was inappropriate to continue to treat CMHCs and hospital-based providers in the same manner regarding payment, particularly in light of such disparate differences in costs. We also were concerned that paying hospital-based PHPs at a lower rate than their cost structure reflects could lead to hospital-based PHP closures and possible access problems for Medicare beneficiaries because hospital-based PHPs are located throughout the country and, therefore, offer the widest access to PHP services. In contrast, CMHC-based PHPs are largely concentrated in certain geographical areas with particular prevalence in Florida, Texas, and Louisiana. Creating the four payment rates (two for CMHCs and two for hospital-based PHPs) based on each provider's data supported continued access to the PHP benefit, while also providing appropriate payment based on the unique cost structures of CMHCs and hospital-based PHPs. In addition, separation of data by provider type was supported by several hospital-based PHP commenters who responded to the CY 2011 OPPS/ASC proposed rule (75 FR 71992).

For CY 2011, we instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. For CY 2011, under the transition methodology, CMHC PHP APCs Level I and Level II per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median and then adding that number to the CY 2011 final CMHC median. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for PHP services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

After publication of the CY 2011 OPPS/ASC final rule with comment period, a CMHC and one of its patients filed an application for a preliminary injunction, challenging the OPPS payment rates for PHP services provided by CMHCs in CY 2011 as adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71995). We refer readers to the court case, *Paladin Cmty. Mental Health Ctr.* v. *Sebelius,* No. 10–949, 2011 WL 3102049 (W.D.Tex. 2011), *aff'd,* No. 11–50682, 2012 WL 2161137 (5th Cir. June 15, 2012) (*Paladin*). The plaintiffs in the *Paladin* case challenged the agency's use of cost data derived from both hospitals and CMHCs in determining the relative payment weights for the OPPS payment rates for PHP services furnished by CMHCs, alleging that section 1833(t)(2)(C) of the Act requires that such relative payment weights be based on cost data derived solely from hospitals. As discussed above, section 1833(t)(2)(C) of the Act requires CMS to ''establish relative payment weights for covered OPD services (and any groups of such services . . .) . . . based on . . . hospital costs.'' Numerous courts have held that ''based on'' does not mean ''based exclusively on.'' On July 25, 2011, the District Court dismissed the plaintiffs' complaint and application for a preliminary injunction for lack of subject-matter jurisdiction, which the plaintiffs appealed to the United States Court of Appeals for the Fifth Circuit. On June 15, 2012, the Court of Appeals affirmed the District Court's dismissal for lack of subject-matter jurisdiction and found that the Secretary's payment rate determinations for PHP services are not a facial violation of a clear statutory mandate. (*Paladin* at *6).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for PHP services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for hospital-based PHP services based exclusively on hospital data. The statute is reasonably interpreted to allow the relative payment weights for the OPPS payment rates for PHP services provided by CMHCs to be based solely on CMHC data and relative payment weights for hospital-based PHP services to be based exclusively on hospital data. Section 1833(t)(2)(C) of the Act requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on . . . hospital costs.'' In pertinent part, subparagraph (B) provides that ''the Secretary may establish groups of covered OPD services . . . so that services classified within each group are comparable clinically and with respect to the use of resources.'' In accordance with subparagraph (B), we developed the PHP APCs, as set forth in § 419.31 of the regulations (65 FR 18446 and 18447; 63 FR 47559 through 47562 and 47567 through 47569). As discussed above, PHP services are grouped into APCs.

Based on section 1833(t)(2)(C) of the Act, we believe that the word ''establish'' can be interpreted as applying to APCs at the inception of the OPPS in 2000 or whenever a new APC is added to the OPPS. In creating the original APC for PHP services (APC 0033), we did ''establish'' the initial relative payment weight for PHP services, provided in both hospital-based and CMHC-based settings, only on the basis of hospital data. Subsequently, from CY 2003 through CY 2008, the relative payment weights for PHP services were based on a combination of hospital and CMHC data. For CY 2009, we established new APCs for PHP services based exclusively on hospital data. Specifically, we adopted a two-tiered APC methodology (in lieu of the original APC 0033) under which CMS paid one rate for days with 3 services (APC 0172) and a different payment rate for days with 4 or more services (APC 0173). These two new APCs were established using only hospital data. For CY 2011, we added two new APCs (APCs 0175 and 0176) for PHP services provided by hospitals and based the relative payment weights for these APCs solely on hospital data. APCs 0172 and 0173 were designated for PHP services provided by CMHCs and were based on a mixture of hospital and CMHC data. As the Secretary argued in the *Paladin* case, the courts have consistently held that the phrase ''based on'' does not mean ''based exclusively on.'' Thus, the relative payment weights for the two APCs for PHP services provided by CMHCs in CY 2011 were ''based on'' hospital data, no less than the relative payment weights for the two APCs for hospital-based PHP services.

Although we used hospital data to establish the relative payment weights for APCs 0033, 0172, 0173, 0175, and 0176 for PHP services, we believe that

we have the authority to discontinue the use of hospital data in determining the OPPS relative payment weights for PHP services provided by CMHCs. Other parts of section 1833(t)(2)(C) of the Act make plain that the data source for the relative payment weights is subject to change from one period to another. Section 1833(t)(2)(C) of the Act provides that, in establishing the relative payment weights, ''the Secretary shall [ ] us[e] data on claims from 1996 and us[e] data from the most recent available cost reports.'' We used 1996 data (in addition to 1997 data) in determining only the original relative payment weights for 2000. In the ensuing calendar year updates, we continually used more recent cost report data.

Moreover, section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.'' For purposes of the CY 2012 update, we exercised our authority under section 1833(t)(9)(A) of the Act to change the data source for the relative payment weights for PHP services provided by CMHCs based on ''new cost data, and other relevant information and factors.''

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs, on geometric means rather than on the medians. For CY 2013, we established the four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims data for each provider type. We refer readers to the CY 2013 OPPS/ASC final rule with comment period for a more detailed discussion (77 FR 68406 through 68412).

B. Proposed PHP APC Update for CY 2014

For CY 2014, we are proposing to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. We computed proposed CMHC PHP APC geometric mean per diem costs for Level I (3 services per day) and Level II (4 or more services per day) PHP services using only CY 2012 CMHC claims data, and proposed hospital-based PHP APC geometric mean per diem costs for Level I and Level II PHP services using only CY 2012 hospital-based PHP claims data. These proposed geometric mean per diem costs are shown in Table 30 below.

TABLE 30—PROPOSED CY 2014 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2012 CLAIMS DATA

APC	Group title	Proposed geometric mean per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$94.51
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	106.20
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	212.85
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	215.13

For CY 2014, the proposed geometric mean per diem costs for days with 3 services (Level I) is approximately $94.51 for CMHCs and approximately $212.85 for hospital-based PHPs. The proposed geometric mean per diem costs for days with 4 or more services (Level II) is approximately $106.20 for CMHCs and approximately $215.13 for hospital-based PHPs. Therefore, the proposed geometric mean per diem costs for CMHCs continue to be substantially lower than the proposed geometric mean per diem costs for hospital-based PHPs for the same level of service provided, which indicates that there continues to be fundamental differences between the cost structures of CMHCs and hospital-based PHPs.

The CY 2014 proposed geometric mean per diem costs for CMHCs calculated under the proposed CY 2014 methodology using CY 2012 claims data have remained relatively constant when compared to the CY 2013 final geometric mean per diem costs for CMHCs established in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68412), with proposed geometric mean per diem costs for Level I PHP services increasing from approximately $87 to approximately $95 for CY 2014, and proposed geometric mean per diem costs for Level II PHP services decreasing from approximately $113 to approximately $106 for CY 2014.

The CY 2014 proposed geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2014 methodology using CY 2012 claims data show more variation when compared to the CY 2013 final geometric mean per diem costs for hospital-based PHPs, with proposed geometric mean per diem costs for Level I PHP services increasing from approximately $186 to approximately $213 for CY 2014, and proposed geometric mean per diem costs for Level II PHP services decreasing from approximately $235 to approximately $215 for CY 2014.

In summary, the proposed CY 2014 geometric mean per diem costs for the PHP APCs are shown in Tables 31 and 32 below. We are inviting public comments on these proposals.

TABLE 31—PROPOSED CY 2014 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC PHP SERVICES

APC	Group title	Proposed geometric mean per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$94.51
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	106.20

TABLE 32—PROPOSED CY 2014 GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

APC	Group title	Proposed geometric mean per diem costs
0175	Level I Partial Hospitalization (3 services) for Hospital-based PHPs	$212.85
0176	Level II Partial Hospitalization (4 or more services) for Hospital-based PHPs	215.13

C. Discussion of Possible Future Initiatives and Request for Public Comments

We are considering a number of possible future initiatives that may help to ensure the long-term stability of PHPs and further improve the accuracy of payment for PHP services. Along with our broad, ongoing objectives of ensuring stability of the PHP benefit and promoting payment accuracy for PHPs, we want to ensure that PHPs are used by individuals who are specifically in need of such services. The PHP benefit was designed to assist individuals with an acute exacerbation of a psychiatric illness to manage debilitating symptoms and prevent the need for admission and readmission into hospitals. Accordingly, we are considering a number of possible future modifications to certain aspects of the PHP benefit. We are not proposing new Medicare policy in this discussion of possible future modifications. Instead, we are requesting public comments on possible future initiatives.

Under the current methodology, we use the most recent claims data to compute geometric mean per diem costs for Level I (3 services per day) and Level II (4 or more services per day) PHP services for CMHCs and for hospital-based PHPs. We are interested in examining the payment structure for PHP services to determine alternative methodologies to pay for PHP services that would reduce unnecessary care while maintaining or increasing the quality of care. We are inviting public comments on alternative payment methodologies.

One of the areas on which we would like to receive public comments is whether payment based on an episode of care, or a per diem similar to the inpatient psychiatric facility (IPF) PPS, would result in more appropriate payment for PHP services than the current payment structure. The IPF PPS is a per diem prospective payment system for inpatient psychiatric hospital services furnished in psychiatric hospitals, and psychiatric units in acute care hospitals and critical access hospitals. The IPF PPS base rate is adjusted to account for patient and facility characteristics that contribute to higher costs per day, including age, diagnosis-related group assignment, comorbidities, days of the stay, geographic wage area, rural location, teaching status, cost of living for IPFs located in Alaska and Hawaii, and the presence of a qualifying emergency department. The IPF PPS methodology includes a payment provision for interrupted stays, additional payment for outlier cases, and a per treatment payment for electroconvulsive therapy (ECT) treatments. For detailed information regarding the implementation of the IPF PPS, we refer readers to the FY 2005 IPF PPS final rule published in the **Federal Register** on November 15, 2004 (69 FR 66922). To find additional information about the IPF PPS, we refer readers to the CMS Web site at: *http://www.cms.hhs.gov/inpatientpsychfacilpps*.

Another area on which we would like to receive public comments is on physician certification/recertification that the individual would require inpatient psychiatric care in the absence of PHP services. In order for a hospital or CMHC to be paid for partial hospitalization services on behalf of a Medicare beneficiary, a physician must certify (and recertify when such services are furnished over a period of time), among other things, that the individual would require inpatient psychiatric care in the absence of such services. In addition, an individualized written plan of treatment for furnishing such services must be established and reviewed periodically by a physician, and such services must be furnished while the individual is under the care of a physician (We refer readers to 42 CFR 424.24(e)).

Currently, the recertification requirements specify that the physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment. The recertification is required as of the 18th day of partial hospitalization services. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days. We are inviting public comments on whether the current requirement under § 424.24(e)(3)(ii) of the regulations, which requires the first recertification by the physician to be as of the 18th day of partial hospitalization services, reflects current PHP treatment practices. Specifically, we are interested in whether the first recertification date should be changed to some other standard that accords with best practices and why.

With respect to the individualized written plan of treatment for furnishing partial hospitalization services, as discussed above, a physician must establish and periodically review the written plan of treatment. The written plan of treatment sets forth the physician's diagnosis, the type, amount, duration, and frequency of the services, and the treatment goals under the written plan. The physician determines the frequency and duration of the PHP services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition. (We refer readers to § 424.24(e)(2) of the regulations.) We are interested in what requirements should be included in the written plan of treatment to better direct PHP resources toward appropriate discharge and follow-up with appropriate support services. Specifically, we are inviting public comments on two issues: (1) The best way that discharge from a PHP be expedited for those individuals no longer at risk of inpatient psychiatric hospitalization; and (2) whether the written plan of treatment requirements under § 424.24(e)(2)(i)(C), which require that the written plan of treatment set forth the treatment goals, should be revised to require that specific actions be taken by the physician and/or staff to assist a beneficiary in transitioning from a PHP to a lower level of care. For example, we are interested in whether the written plan of treatment should require that, upon discharge, patients have written instructions that include:

- A full list of their medications, dosages and any necessary prescriptions;
- Their next scheduled appointment with a psychiatrist or qualified practitioner who may bill for his or her professional services under Medicare Part B, including the phone number,

address, and appointment date and time;

- Confirmed place to live in a stable environment with support services; and
- Other care coordination information.

We also are interested in receiving public feedback about quality measures for a PHP. Quality health care is a high priority for CMS. We implement quality initiatives to ensure quality health care for Medicare beneficiaries through accountability and public disclosure. We use quality measures under various quality initiatives, which utilize pay-for-reporting and public reporting mechanisms. We are requesting public comments on quality measures for PHP services for future consideration. Specifically, if we were to establish quality measures for PHP services and require quality data reporting, what should be included in those measures? In addition, should the quality measures be similar or identical to those measures established for IPFs under the IPF Quality Reporting (IPFQR) Program?

We would appreciate feedback on all of these areas for future consideration. Therefore, we are inviting public comments on these issues.

D. Proposed Separate Threshold for Outlier Payments to CMHCs

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), after examining the costs, charges, and outlier payments for CMHCs, we believed that establishing a separate OPPS outlier policy for CMHCs would be appropriate. A CMHC-specific outlier policy would direct OPPS outlier payments towards genuine cost of outlier cases, and address situations where charges were being artificially increased to enhance outlier payments. We created a separate outlier policy that would be specific to the estimated costs and OPPS payments provided to CMHCs. We note that, in the CY 2009 OPPS/ASC final rule with comment period, we established an outlier reconciliation policy to comprehensively address charging aberrations related to OPPS outlier payments (73 FR 68594 through 68599). Therefore, beginning for CY 2004, we designated a portion of the estimated OPPS outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

The separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004, and $0.5 million in outlier payments to CMHCs in CY 2005. In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments. We believe that this difference in outlier payments indicates that the separate outlier threshold for CMHCs has been successful in keeping outlier payments to CMHCs in line with the percentage of OPPS payments made to CMHCs.

In this CY 2014 OPPS/ASC proposed rule, we are proposing to continue designating a portion of the estimated 1.0 percent outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS in CY 2014, excluding outlier payments. CMHCs are projected to receive 0.18 percent of total OPPS payments in CY 2014, excluding outlier payments. Therefore, we are proposing to designate 0.0018 percent of the estimated 1.0 percent outlier target amount for CMHCs, and establish a threshold to achieve that level of outlier payments. Based on our simulations of CMHC payments for CY 2014, we are proposing to continue to set the threshold for CY 2014 at 3.40 times the highest CMHC PHP APC payment rate (that is, APC 0173 (Level II Partial Hospitalization)). We continue to believe that this approach would neutralize the impact of inflated CMHC charges on outlier payments and better target outlier payments to those truly exceptionally high-cost cases that might otherwise limit beneficiary access. In addition, we are proposing to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2014, we are proposing to continue to pay 50 percent of CMHC per diem costs over the threshold. In section II.G. of this proposed rule, for the hospital outpatient outlier payment policy, we are proposing to set a dollar threshold in addition to an APC multiplier threshold. Because the PHP APCs are the only APCs for which CMHCs may receive payment under the OPPS, we would not expect to redirect outlier payments by imposing a dollar threshold. Therefore, we are not proposing to set a dollar threshold for CMHC outlier payments.

In summary, we are proposing to establish that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. We are inviting public comments on these proposals.

IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient list) and, therefore, will not be paid by Medicare under the OPPS; and on the criteria that we use to review the inpatient list each year to determine whether or not any procedures should be removed from the list.

B. Proposed Changes to the Inpatient List

For the CY 2014 OPPS, we are proposing to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65835)) of reviewing the current list of procedures on the inpatient list to identify any procedures that may be removed from the list. The established criteria upon which we make such a determination are as follows:

1. Most outpatient departments are equipped to provide the services to the Medicare population.

2. The simplest procedure described by the code may be performed in most outpatient departments.

3. The procedure is related to codes that we have already removed from the inpatient list.

4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.

5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

Using this methodology, we did not identify any procedures that potentially could be removed from the inpatient list for CY 2014. Therefore, we are proposing to not remove any procedures from the inpatient list for CY 2014.

The complete list of codes that we are proposing to be paid by Medicare in CY 2014 only as inpatient procedures is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

X. Proposed Nonrecurring Policy Changes

A. Supervision of Hospital Outpatient Therapeutic Services

1. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in CAHs and Certain Small Rural Hospitals

In the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, respectively), we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare in hospitals as well as in provider-based departments of hospitals, as set forth in the CY 2000 OPPS final rule with comment period (65 FR 18525). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60575 through 60591), we finalized a technical correction to the title and text of the applicable regulations at 42 CFR 410.27 to clarify that this standard applies in CAHs as well as hospitals. In response to concerns expressed by the hospital community, in particular CAHs and small rural hospitals, that they would have difficulty meeting this standard, on March 15, 2010, we instructed all Medicare contractors not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs from January 1, 2010 through December 31, 2010, while the agency revisited the supervision policy during the CY 2011 OPPS/ASC rulemaking cycle.

Due to continued concerns expressed by CAHs and small rural hospitals, we extended this notice of nonenforcement (''enforcement instruction'') as an interim measure for CY 2011, and expanded it to apply to small rural hospitals having 100 or fewer beds (75 FR 72007). We continued to consider the issue further in our annual OPPS notice-and-comment rulemaking, and implemented an independent review process to obtain advice from the Hospital Outpatient Payment Panel (the Panel) on this matter (76 FR 74360 through 74371). Under this process used since CY 2012, the Panel considers and advises CMS regarding stakeholder requests for changes in the required level of supervision of individual hospital outpatient therapeutic services. We extended the enforcement instruction the past 2 years (through CY 2012 and CY 2013) to provide hospitals with adequate opportunity to become familiar with the new independent review process and submit evaluation requests, and to meet the required supervision levels for all hospital outpatient therapeutic services (we refer readers to 76 FR 74371 and 77 FR 68425). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68426), we stated that we expect CY 2013 to be the final year that the enforcement instruction would be in effect, as during this year there would be additional opportunities for stakeholders to bring their issues to the Panel, and for the Panel to evaluate and provide us with recommendations on those issues. The current enforcement instruction is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html?redirect=/HospitalOutpatientPPS/01_overview.asp*.

In CY 2012 and CY 2013, the Panel met and considered several requests from CAHs and other stakeholders for changes in the required level of supervision for observation and other services. Based on the Panel's recommendations, we modified our supervision requirements to provide that most of the services considered may be furnished under general supervision, in accordance with applicable Medicare regulations and policies. These decisions are posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPS-General-Supervision.pdf*. We did not receive any requests from stakeholders for evaluation of the supervision levels of any other hospital outpatient therapeutic services at the March 2013 Panel meeting. We continue to believe that direct supervision is the most appropriate level of supervision for most hospital outpatient therapeutic services under the ''incident to'' provisions of section 1861(s)(2)(B) of the Act, as we discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72006). We believe the independent Panel review advisory process has proved an effective means for the hospital community to identify hospital outpatient therapeutic services that can safely be furnished under general supervision, where the supervising practitioner does not have to be immediately available in person to provide assistance and direction. We encourage hospitals to continue using the Panel process for bringing services to CMS' attention that may not require the immediate availability of a supervising practitioner, especially where it is possible to reduce the burden on the workforce available to small rural hospitals and CAHs while ensuring the quality and safety of patient care. We encourage hospitals and CAHs to continue using the established Panel process to request changes they believe would be appropriate in supervision levels for individual hospital outpatient therapeutic services. Instructions for submitting evaluation requests are available on the Panel Web site at *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*).

We believe it is appropriate to allow the enforcement instruction to expire at the end of CY 2013, to ensure the quality and safety of hospital and CAH outpatient therapeutic services paid by Medicare. For CY 2014, we anticipate allowing the enforcement instruction to expire, such that all outpatient therapeutic services furnished in hospitals and CAHs would require a minimum of direct supervision unless the service is on the list of services that may be furnished under general supervision or is designated as a nonsurgical extended duration therapeutic service (the list of services is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPS-General-Supervision.pdf*). We are interested in receiving public comments on any potential impacts on access to care and quality of care for specific services that may result from allowing the enforcement instruction to expire at the end of CY 2013. We are requesting public comments on specific services for which CAHs and small rural hospitals anticipate difficulty furnishing the required direct supervision, including specific factors that may contribute to the lack of available staff.

2. Supervision Requirements for Observation Services

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71999 through 72013), we revised the supervision requirements for observation services furnished in the hospital by designating observation services (HCPCS codes G0378 (Hospital observation services, per hour) and G0379 (Direct admission of patient for observation care)) as nonsurgical extended duration therapeutic services (''extended duration services''). As we provided in the CY 2011 OPPS/ASC final rule with comment period and 42 CFR 410.27(a)(1)(iv)(E), extended duration services require direct supervision at the initiation of the service, which may be followed by general supervision for the remainder of

the service at the discretion of the supervising physician or appropriate nonphysician practitioner, once that practitioner has determined that the patient is stable. The determination by the supervising physician or appropriate nonphysician practitioner that the beneficiary is stable and may be transitioned to general supervision must be documented in progress notes or in the medical record (75 FR 72011).

Since we designated observation services as extended duration services, we have received several inquiries from stakeholders regarding whether Medicare requires multiple evaluations of the beneficiary during the provision of observation services. Specifically, stakeholders asked whether, once the supervising physician or appropriate nonphysician practitioner transitions the beneficiary to general supervision and documents the transition in the medical record, Medicare require further assessment of the beneficiary either per hour (because observation services are billed per hour) or at some other point during provision of the service. We are clarifying that, for observation services, if the supervising physician or appropriate nonphysician practitioner determines and documents in the medical record that the beneficiary is stable and may be transitioned to general supervision, general supervision may be furnished for the duration of the service. Medicare does not require an additional initiation period(s) of direct supervision during the service. We believe that this clarification will assist hospitals in furnishing the required supervision of observation services without undue burden on their staff.

B. Application of Therapy Caps in CAHs

For outpatient physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) (collectively, ''outpatient therapy'') services covered under Medicare Part B, section 1833(g) of the Act applies annual, per beneficiary limitations on incurred expenses, commonly referred to as ''therapy caps.'' There is one therapy cap for OT services and another separate therapy cap for PT and SLP services combined. In the CY 2014 Medicare Physician Fee Schedule (MPFS) proposed rule, we are proposing to subject outpatient therapy services that are furnished by a CAH to the therapy caps, the exceptions process, and the manual medical review process beginning on January 1, 2014. The American Taxpayer Relief Act of 2012 (Pub. L. 112–240) required that therapy services furnished by a CAH during 2013 are counted toward the therapy caps using the MPFS rate, and we are proposing to continue this methodology for 2014 and subsequent years. CAHs would still be paid for therapy services under the reasonable cost methodology for CAH outpatient services described at section 1834(g) of the Act. We refer readers to the CY 2014 MPFS proposed rule for detailed information about the proposed application of the therapy caps and related provisions to CAHs. We are including in this CY 2014 OPPS/ASC proposed rule a reference to this proposal as an additional means to direct CAHs' attention to our proposal in the CY 2014 MPFS proposed rule. We refer readers to the CY 2014 MPFS proposed rule for instructions for submitting public comments related to this proposal to apply the therapy cap to services furnished by CAHs. We look forward to reviewing the comments on this proposal.

C. Requirements for Payment of Outpatient Therapeutic (''Incident To'') Hospital or CAH Services

1. Overview

In this section, we are proposing to amend the Medicare conditions of payment for therapeutic outpatient hospital or CAH services and supplies furnished ''incident to'' a physician's or nonphysician practitioner's service (which we refer to as hospital or CAH outpatient therapeutic services) to require that individuals furnishing these services do so in compliance with applicable State law. Under current policy, we generally defer to hospitals to ensure that State scope of practice and other State rules relating to health care delivery are followed, such that these services are performed only by qualified personnel in accordance with all applicable laws and regulations. We are proposing to revise the existing regulations to explicitly require that individuals who perform hospital or CAH outpatient therapeutic services must do so in compliance with applicable State laws and regulations as a condition of payment under Medicare Part B. In this section of this proposed rule, we are using the term ''hospital'' to include a CAH unless otherwise specified. Although the term ''hospital'' does not generally include a CAH, section 1861(e) of the Act provides that the term ''hospital'' includes a CAH if the context otherwise requires. We believe it would be appropriate to apply our proposed policy regarding compliance with applicable State law, as we do for other conditions of payment for hospital outpatient therapeutic services, to CAHs as well as other hospitals.

2. Background

Section 1861(s)(2)(B) of the Act establishes the benefit category for hospital ''incident to'' medical and other health services, which are paid under Medicare Part B. The statute specifies that ''incident to'' services are ''hospital services (including drugs and biological which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services.'' In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74369 through 74370), we clarified that Medicare defines these services as hospital outpatient therapeutic services, which are, according to our policy, furnished ''incident to'' a physician's service even when described by benefit categories other than the specific ''incident to'' provision in section 1861(s)(2)(B) of the Act (for example, radiation therapy services described under section 1861(s)(4) of the Act). Because hospital outpatient therapeutic services are furnished ''incident to'' a physician's professional service, we believe the conditions of payment that derive from the ''incident to'' nature of the services paid under section 1861(s)(2)(B) of the Act apply to all hospital outpatient therapeutic services, including those described under benefit categories other the specific ''incident to'' provision in section 1861(s)(2)(B) of the Act.

In addition to the requirements of the statute, the regulation at 42 CFR 410.27 sets forth specific requirements that must be met in order for hospital to be paid under Medicare Part B for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service (hospital or CAH outpatient therapeutic services). Section 410.27 describes hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's services as therapeutic services and provides the conditions of payment. Specifically, § 410.27(a) provides that Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service. These are defined, in part, as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered, if they are furnished—

- By or under arrangements made by the participating hospital or CAH,

except in the case of a SNF resident as provided in 42 CFR 411.15(p);

- As an integral although incidental part of a physician's or nonphysician practitioner's services;
- In the hospital or CAH or in a department of the hospital or CAH, as defined in 42 CFR 413.65 [a provider-based department]; and
- Under the direct supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner. For purposes of this section, ''nonphysician practitioner,'' as defined in § 410.27(g), means a clinical psychologist, licensed clinical social worker, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.

Sections 410.27(b) through (f) provide additional conditions of payment for partial hospitalization services, drugs and biologicals, emergency services, and services furnished by an entity other than the hospital (or CAH). We commonly refer to the services described in § 410.27 as ''incident to'' services.

In recent years, we have discussed and refined the supervision regulations under § 410.27, which are conditions of Medicare Part B payment for hospital outpatient ''incident to'' (''therapeutic'') services. For example, we have discussed our belief that direct supervision is the most appropriate level of supervision for most of these services, unless personal supervision or personal performance of the services by the physician or nonphysician practitioner is more appropriate, given the incident to nature of the services as an integral although incidental part of a physician's or nonphysician practitioner's services (74 FR 60584, 75 FR 72006, and 76 FR 42281). We have stated our historical interpretation of section 1861(s)(2)(B) of the Act, specifically, that ''incident to'' services are furnished under the order of a physician (or nonphysician practitioner), the physician is involved in the management of the patient, and the physician supervises the provision of those services when he or she does not provide them directly (75 FR 72006). This is reflected in our requirement for a minimum of direct supervision, except for a limited set of services that may be furnished under general supervision or are designated as nonsurgical extended duration therapeutic services which require direct supervision initially with potential transition to general supervision (we refer readers to the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPS-General-Supervision.pdf*).

In 42 CFR 410.27(a)(1)(iv), we regulate the qualifications of physicians and nonphysician practitioners supervising other personnel that are personally performing a service, or part of a service: ''(C) Nonphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§ 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77'' and ''(D) For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively.''

Similarly, we provide in the Medicare Benefit Policy Manual (MBPM, Pub. 100–02) that hospital outpatient therapeutic services and supplies must be furnished under the order of a physician or other practitioner practicing within the extent of the Act, the Code of Federal Regulations, and State law (Chapter 6, Section 20.5.2 of the MBPM). Section 20.5.2 of the MBPM specifies that the services must be furnished by hospital personnel under the appropriate supervision of a physician or nonphysician practitioner in accordance with 42 CFR 410.27 and 482.12. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician responsible for care of the patient. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, when necessary, to change the treatment regimen. A hospital service or supply would not be considered incident to a physician's service if the attending physician merely wrote an order for the services or supplies and referred the patient to the hospital without being involved in the management of that course of treatment.

Central to the issue of services that hospitals may bill to Medicare that are not performed personally by the physician is the assessment of the qualifications of the individuals to whom the services are delegated. As medical practice has evolved over time, the services performed in the hospital outpatient setting have expanded to include more complicated services such as advanced surgery and a complex variety of radiation therapy. In addition, the types of services that can be furnished ''incident to'' a physician's or nonphysician practitioner's services have increased. Under current Medicare Part B payment policy, we generally defer to hospitals to ensure that State scope of practice laws are followed and that the personnel who furnish hospital outpatient therapeutic (''incident to'') services are licensed and are otherwise qualified to do so. Specifically, we have stated that, considering that hospitals furnish a wide array of complex outpatient services and procedures, including surgical procedures, we would expect that hospitals have the credentialing procedures, bylaws, and other policies in place to ensure that hospital outpatient services furnished to Medicare beneficiaries are being provided only by qualified practitioners in accordance with all applicable laws and regulations (74 FR 60584; Chapter 6, Section 20.5.4 of the MBPM). However, our payment regulations do not contain restrictions on the types of auxiliary personnel that can perform hospital outpatient therapeutic (''incident to'') services, other than rules relating to supervision by a physician or qualified nonphysician practitioner, and do not specifically require that performance of these services be in compliance with applicable State law. Over the past years, several situations have come to our attention where Medicare was billed for ''incident to'' services that were performed by an individual who did not meet the State standards for those services in the State in which services were performed. The physician or nonphysician practitioner billing for the services would have been permitted under State law to personally furnish the services, but the services were actually provided by other individuals who were not in compliance with State law in providing the particular services (or aspect of the services).

Although we would expect that all hospital services for which Medicare payment is made would be furnished in accordance with State law, the Medicare requirements for hospital outpatient therapeutic services and supplies incident to a physician's services (§ 410.27, discussed above) do not specifically make compliance with State law a condition of payment for services (or aspects of services) and supplies furnished and billed as ''incident to'' services. Nor do any of the regulations regarding hospital outpatient therapeutic services and supplies incident to the services of nonphysician practitioners contain this requirement.

Thus, Medicare has had limited recourse when hospital outpatient therapeutic (''incident to'') services are not furnished in compliance with State law.

In 2009, the Office of the Inspector General (OIG) issued a report entitled ''Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services'' (OEI–09–06–00430) that considered, in part, the qualifications of auxiliary personnel providing ''incident to'' physician services. After finding that services were being provided and billed to Medicare by auxiliary personnel ''. . . who did not possess the required licenses or certifications according to State laws, regulations, and/or Medicare rules,'' the OIG recommended that we revise the ''incident to'' rules to, among other things, ''require that physicians who do not personally perform the services they bill to Medicare ensure that no persons except . . . nonphysicians who have the necessary training, certification, and/or licensure pursuant to State laws, State regulations, and Medicare regulations personally perform the services under the direct supervision of a licensed physician.'' We are proposing amendments to our regulations in order to address this recommendation.

To ensure that the practitioners and other personnel providing hospital outpatient therapeutic services to Medicare beneficiaries incident to a physician's or nonphysician practitioner's service do so in accordance with the requirements of the State in which the services are furnished, and to ensure that Medicare payments can be recovered when such services are not furnished in compliance with the State law, we are proposing to add a new condition of payment to the ''incident to'' regulations at § 410.27, Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions. Specifically, we are proposing to add a provision under a new paragraph (a)(1)(vi) under § 410.27 to provide that ''Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service . . . if they are furnished ''In accordance with applicable State law.'' The proposed policy would recognize the role of States in establishing the licensure and other qualifications of physicians and other health care professionals for the delivery of hospital (or CAH) outpatient therapeutic services.

This proposal is consistent with other areas of the Medicare program where CMS defers to State rules regarding the delivery of hospital services. For example, the hospital conditions of participation (CoPs) at 42 CFR 482.12(c)(2) defer to State law in determining who can admit patients as inpatients of a hospital: ''Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.'' The CoP also provides that, ''If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section (that lists practitioners that must care for Medicare patients), that patient is under the care of a doctor of medicine or osteopathy.'' Thus, in determining who may admit inpatients to a hospital, Medicare defers to State law rules. Also, as we stated in a recent rule addressing credentialing and privileging and telemedicine services under the CoPs (77 FR 29047): ''CMS recognizes that practitioner licensure laws and regulations have traditionally been, and continue to be, the provenance of individual States, and we are not seeking to preempt State authority in this matter.'' We believe it is appropriate to similarly require that all hospital outpatient services furnished incident to a physician's or nonphysician practitioner's services be furnished in accordance with State law requirements. As evidenced by these examples, throughout the Medicare program the qualifications required for the delivery of health care services are generally determined with reference to State law. In addition to the health and safety benefits we believe would accrue to the Medicare patient population, this approach would assure that Federal dollars are not expended for services that do not meet the standards of the States in which they are being furnished, and provides the ability for the Federal government to recover funds paid where services and supplies are not furnished in accordance with State law.

This proposal would not impose any new requirements on hospitals billing the Medicare program because practitioners and other personnel furnishing services in a given State would already be required to comply with the laws of that State. This regulatory change would simply adopt the existing requirements as a condition of payment under Medicare. Codifying this requirement would provide the Federal government with a clear basis to deny a claim for Medicare payment when services are not furnished in accordance with applicable State law, and the ability to recover funds, as well as assure that Medicare pays for services furnished to beneficiaries only when the services meet the requirements imposed by the States to regulate health care delivery for the health and safety of their citizens. We welcome public comments on this proposal.

3. Technical Correction

In our review of § 410.27, we noted that paragraph (a) defines therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service as ''all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered.'' Section 1861(s)(2)(B) of the Act describes these services as ''hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services.'' The statute includes in this benefit category ''drugs and biologicals which are not usually self-administered by the patient.'' We are proposing to make a technical correction that would amend the description of these drugs and biologicals at § 410.27(a) to more appropriately reflect the statutory language. Specifically, we are proposing to delete the phrase ''drugs and biologicals that cannot be self-administered'' and replace it with the phrase ''drugs and biologicals which are not usually self-administered.'' Under this proposed technical correction, the language of § 410.27(a) would read, ''Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hopital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered. . . .''

D. Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

In recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physicians' services in a hospital setting (for example, we refer readers to

Ostrom, Carol M., ''Why you might pay twice for one visit to a doctor,'' *Seattle Times,* November 3, 2012, and O'Malley, Ann, Amelia M. Bond, and Robert Berenson, *Rising hospital employment of physicians: better quality, higher costs?* Issue Brief No. 136, Center for Studying Health System Change, August 2011). When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician office. As more physician practices become hospital-based, news articles have highlighted beneficiary liability for an additional ''facility fee,'' which is the payment Medicare makes when services are furnished in a hospital in addition to the payment to the physician. MedPAC has questioned the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments and has recommended that Medicare pay selected hospital outpatient services at the Medicare Physician Fee Schedule (MPFS) rates (MedPAC March 2012 Report to Congress; ''Addressing Medicare Payment Differences across Settings,'' presentation to the Commission on March 7, 2013).

The total payment (including both Medicare program payment and beneficiary cost-sharing) generally is higher when outpatient services are furnished in the hospital outpatient setting rather than a freestanding clinic or a physician office. Both the OPPS and the MPFS establish payment based on the relative resources involved in furnishing a service. In general, we expect hospitals to have overall higher resource requirements than physician offices because hospitals are required to meet the conditions of participation, to maintain standby capacity for emergency situations, and to be available to address a wide variety of complex medical needs in a community. When services are furnished in the hospital setting such as in off-campus provider-based departments, Medicare pays the physician a lower facility payment under the MPFS, but then also pays the hospital under the OPPS. The beneficiary pays coinsurance for both the physician payment and the hospital outpatient payment. The term ''facility fee'' refers to this additional hospital outpatient payment.

Upon acquisition of a physician practice, hospitals frequently treat the practice locations as off-campus provider-based departments of the hospital and bill Medicare for services furnished at those locations under the OPPS. (For further information on the provider-based regulations at § 413.65, we refer readers to *http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2-sec413-65.pdf.* Since October 1, 2002, we have not required hospitals to seek from CMS a determination of provider-based status for a facility that is located off campus. We also do not have a formal process for gathering information on the frequency, type, and payment for services furnished in off-campus provider-based departments of the hospital.

In order to better understand the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments, we are considering collecting information that would allow us to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments. We have considered several potential methods. Claims-based approaches could include creating a HCPCS modifier that could be reported with every code for services furnished in an off-campus provider-based department of a hospital on the CMS–1500 claim form for physician services and the UB–04 (CMS form 1450) for hospital outpatient claims. In addition, we have considered asking hospitals to break out the costs and charges for their provider-based departments as outpatient service cost centers on the Medicare hospital cost report, form 2552–10. We note that some hospitals already break out these costs voluntarily or because of cost reporting requirements for the 340B Drug Discount Program but this practice is not consistent or standardized. We are inviting public comments on the best means for collecting information on the frequency, type, and payment for services furnished in off-campus provider-based departments of hospitals.

XI. Proposed CY 2014 OPPS Payment Status and Comment Indicators

A. Proposed CY 2014 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The complete list of the proposed CY 2014 status indicators and their definitions is displayed in Addendum D1 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The proposed CY 2014 status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The proposed changes to CY 2014 status indicators and their definitions are discussed in detail below.

For CY 2014, we are proposing to create a new status indicator ''J1'' to identify HCPCS codes that are paid under a comprehensive APC. A claim with the new proposed status indicator ''J1'' will trigger a comprehensive APC payment for the claim. The comprehensive APCs that we are proposing to establish are described in detail in section II.A.2.e. of this proposed rule.

For CY 2014, we are proposing to delete status indicator ''X'' and assign ancillary services that are currently assigned status indicator ''X'' to either status indicator ''Q1'' or ''S''. First, services that are proposed to be assigned status indicator ''Q1'' include many minor diagnostic tests that are generally ancillary to and performed with another service. However, services that are proposed to be assigned to status indicator ''Q1'' also may be performed alone. Given the nature of these services and their role in hospital outpatient care, we believe that when these services are performed with another service they should be packaged, but that they should be separately paid when performed alone. Therefore, we believe it is appropriate to conditionally package all ancillary services that are currently assigned to status indicator ''X,'' and are proposing to assign them to status indicator ''Q1.'' We also are proposing that preventive services currently assigned status indicator ''X'' continue to receive separate payment in all cases and be assigned status indicator ''S'' for CY 2014. These proposed changes are discussed in greater detail in section II.A.3. of this proposed rule. In addition, we are proposing to revise the definition of status indicator ''Q1'' by removing status indicator ''X'' from the packaging criteria, so that codes assigned status indicator ''Q1'' are STV-packaged, rather than STVX-packaged, because status indicator ''X'' is proposed for deletion.

For CY 2014, we are proposing to revise the definitions of status indicators ''S'' and ''T'' to remove the word ''significant'' from these definitions. It is no longer necessary to distinguish significant procedures from ancillary services because we are proposing to delete the status indicator that describes ancillary services. We also are proposing to add the word ''service'' to the definitions of status indicators ''S'' and ''T'' to indicate ''procedure or service; not discounted when multiple,'' as applicable to status indicator ''S'' and ''procedure or service; multiple reduction applies,'' as applicable to status indicator ''T.''

In addition, we are proposing to update the definition of status indicator ''A'' for CY 2014. We are proposing to remove ''Routine Dialysis Services for ESRD Patients Provided in a Certified Dialysis Unit of a Hospital'' from the list of items and services applicable for the definition of status indicator ''A'' because these services are not recognized by OPPS when submitted on an outpatient hospital Part B bill type and are instead assigned to status indicator ''B.''

B. Proposed CY 2014 Comment Indicator Definitions

For the CY 2014 OPPS, we are proposing to use the same two comment indicators that are in effect for the CY 2013 OPPS.

- ''CH''—Active HCPCS codes in current and next calendar year; status indicator and/or APC assignment have changed or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

We are proposing to use the ''CH'' comment indicator in this CY 2014 OPPS/ASC proposed rule to indicate HCPCS codes for which the status indicator or APC assignment, or both, are proposed for change in CY 2014 compared to their assignment as of June 30, 2013. We believe that using the ''CH'' indicator in this proposed rule would facilitate the public's review of the changes that we are proposing for CY 2014. Use of the comment indicator ''CH'' in association with a composite APC indicates that the configuration of the composite APC is proposed to be changed in the CY 2014 OPPS/ASC final rule with comment period.

We are proposing to use the ''CH'' comment indicator in the CY 2014 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, would change in CY 2014 compared to their assignment as of December 31, 2013.

In addition, we are proposing that any existing HCPCS codes with substantial revisions to the code descriptors for CY 2014 compared to the CY 2013 descriptors will be labeled with comment indicator ''NI'' in Addendum B to the CY 2014 OPPS/ASC final rule with comment period. However, in order to receive the comment indicator ''NI,'' the CY 2014 revision to the code descriptor (compared to the CY 2013 descriptor) must be significant such that the new code descriptor describes a new service or procedure for which the OPPS treatment may change. We use comment indicator ''NI'' to indicate that these HCPCS codes will be open for comment as part of the CY 2014 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator ''NI,'' we will respond to public comments and finalize their OPPS treatment in the CY 2015 OPPS/ASC final rule with comment period.

In accordance with our usual practice, we are proposing that CPT and Level II HCPCS codes that are new for CY 2014 also will be labeled with comment indicator ''NI'' in Addendum B to the CY 2014 OPPS/ASC final rule with comment period.

Only HCPCS codes with comment indicator ''NI'' in the CY 2014 OPPS/ASC final rule with comment period will be subject to comment. HCPCS codes that do not appear with comment indicator ''NI'' in the CY 2014 OPPS/ASC final rule with comment period will not be open to public comment, unless we specifically request additional comments elsewhere in the final rule with comment period.

We believe that the CY 2013 definitions of the OPPS status indicators continue to be appropriate for CY 2014. Therefore, we are proposing to continue to use those definitions without modification for CY 2014. The proposed definitions are listed in Addendum D2 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

XII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74378 through 74379) and the CY 2013 OPPS/ASC final rule with comment period (77 FR 68434 through 68467).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under § 416.2 and § 416.166 of the regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and that would not be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478).

In the August 2, 2007 final rule, we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through status under the OPPS; (3) certain items and services that we

designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. These covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment (72 FR 42495). Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). In addition, as discussed in detail in section XII.B. of this proposed rule, because we base ASC payment policies for covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, we also provide quarterly update change requests (CRs) for ASC services throughout the year (January, April, July, and October). CMS releases new Level II codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare claims) outside of the formal rulemaking process via these ASC quarterly update CRs. Thus, these quarterly updates are to implement newly created Level II HCPCS and Category III CPT codes for ASC payment and to update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New Category I CPT codes, except vaccine codes, are released only once a year and, therefore, are implemented only through the January quarterly update. New Category I CPT vaccine codes are released twice a year and, therefore, are implemented through the January and July quarterly updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for the process used to update the HCPCS and CPT codes (76 FR 42291).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new procedures, and procedures for which there is revised coding, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. Proposed Treatment of New Codes

1. Proposed Process for Recognizing New Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims: (1) Category I CPT codes, which describe surgical procedures; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule to evaluate each year all new Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures (72 FR 42533 through 42535). In addition, we identify new codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system.

We have separated our discussion below into two sections based on whether we are proposing to solicit public comments in this CY 2014 OPPS/ASC proposed rule (and respond to those comments in the CY 2014 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2014 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2015 OPPS/ASC final rule with comment period).

We note that we sought public comment in the CY 2013 OPPS/ASC final rule with comment period on the new Category I and III CPT and Level II HCPCS codes that were effective January 1, 2013. We also sought public comment in the CY 2013 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2012. These new codes, with an effective date of October 1, 2012, or January 1, 2013, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2013 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2013 OPPS/ASC final rule with comment period. We will respond to public comments and finalize the treatment of these codes under the ASC payment system in the CY 2014 OPPS/ASC final rule with comment period.

2. Proposed Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April 2013 and July 2013 for Which We Are Soliciting Public Comments in This CY 2014 OPPS/ASC Proposed Rule

In the April 2013 and July 2013 CRs, we made effective for April 1, 2013 and July 1, 2013, respectively, a total of nine new Level II HCPCS codes and two new Category III CPT codes that describe covered ASC services that were not addressed in the CY 2013 OPPS/ASC final rule with comment period. In the April 2013 ASC quarterly update (Transmittal 2662, CR 8237, dated March 1, 2013), we added one new surgical Level II HCPCS code and three new drug and biological Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services, respectively. Table 33 below lists the new Level II HCPCS codes that were implemented April 1 2013, along with their proposed payment indicators for CY 2014.

In the July 2013 quarterly update (Transmittal 2717, Change Request 8328, dated May 31, 2013), we added one new surgical Level II HCPCS code to the list of covered surgical procedures and, one new vaccine Level II HCPCS code, and three new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 34 below lists the new Level II HCPCS codes that were implemented July 1, 2013, along with their proposed payment indicators and proposed ASC payment rates for CY 2014.

We assigned payment indicator ''K2'' (Drugs and biologicals paid separately when provided integral to a surgical

procedure on the ASC list; payment based on OPPS rate) to the six new drug and biological Level II HCPCS codes that are separately paid when provided in ASCs. We assigned payment indicator ''L1'' (Influenza vaccine; pneumococcal vaccine. Packaged item/service; no separate payment made) to the new vaccine Level II HCPCS code and payment indicator ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) to the two new surgical Level II HCPCS codes.

We are soliciting public comment on the proposed CY 2014 ASC payment indicators and payment rates for the covered surgical procedures and covered ancillary services listed in Tables 33 and 34 below. Those HCPCS codes became payable in ASCs, beginning April 1, or July 1, 2013, and are paid at the ASC rates posted for the appropriate calendar quarter on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.*

The HCPCS codes listed in Table 33 are included in Addenda AA or BB to this proposed rule (which is available via the Internet on the CMS Web site). We note that all ASC addenda are only available via the Internet on the CMS Web site. Because the payment rates associated with the new Level II HCPCS codes that became effective July 1, 2013 (listed in Table 34 of this proposed rule) are not available to us in time for incorporation into the Addenda to this OPPS/ASC proposed rule, our policy is to include these HCPCS codes and their proposed payment indicators and payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates will be included in the appropriate Addendum to the CY 2014 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2013 ASC quarterly update CR and their proposed CY 2014 payment rates (based on July 2013 ASP data) that are displayed in Table 34 are not included in Addenda AA or BB to this proposed rule (which is available via the Internet on the CMS Web site). The final list of ASC covered surgical procedures and covered ancillary services and the associated payment weights and payment indicators will be included in Addenda AA or BB to the CY 2014 OPPS/ASC final rule with comment period, consistent with our annual update policy.

We are soliciting public comment on these proposed payment indicators and the proposed payment rates for the new Level II HCPCS codes that were newly recognized as ASC covered surgical procedures or covered ancillary services in April 2013 and July 2013 through the quarterly update CRs, as listed in Tables 33 and 34 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2014 OPPS/ASC final rule with comment period.

TABLE 33—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2013

CY 2013 HCPCS Code	CY 2013 Long descriptor	Proposed CY 2014 payment indicator
C9130	Injection, immune globulin (Bivigam), 500 mg	K2
C9297	Injection, omacetaxine mepesuccinate, 0.01 mg	K2
C9298	Injection, ocriplasmin, 0.125 mg	K2
C9735	Anoscopy; with directed submucosal injection(s), any substance	G2

TABLE 34—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2013

CY 2013 HCPCS Code	CY 2013 Long descriptor	Proposed CY 2014 payment indicator	Proposed CY 2014 payment rate
C9131	Injection, ado-trastuzumab emtansine, 1 mg	K2	$29.40
C9736	Laparoscopy, surgical, radiofrequency ablation of uterine fibroid(s), including intraoperative guidance and monitoring, when performed.	G2	2,010.00
Q2033	Influenza Vaccine, Recombinant Himagglutinin Antigens, for Intramuscular Use (Flublok) ..	L1	N/A
Q2050*	Injection, Doxorubicin Hydrochloride, Liposomal, Not Otherwise Specified, 10 mg	K2	545.44
Q2051*	Injection, Zoledronic Acid, Not Otherwise Specified, 1 mg	K2	196.42

*__Note:__ HCPCS code Q2050 replaced code J9002 and HCPCS code Q2051 replaced HCPCS codes J3487 and J3488 beginning July 1, 2013.

Through the July 2013 quarterly update CR, we also implemented ASC payment for two new Category III CPT codes as ASC covered ancillary services, effective July 1, 2013. These codes are listed in Table 35 below, along with their proposed payment indicators and proposed payment rates for CY 2014. Because the payment rates associated with the new Category III CPT codes that became effective for July are not available to us in time for incorporation into the Addenda to this OPPS/ASC proposed rule, our policy is to include the codes, their proposed payment indicators, and proposed payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. The codes listed in Table 35 of this proposed rule and their final payment indicators and rates will be included in Addendum BB to the CY 2014 OPPS/ASC final rule with comment period.

We are proposing to assign payment indicator ''Z2'' (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight) to the two new Category III CPT codes implemented in July 2013. ASC covered ancillary services are certain items and services that are integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS. We are soliciting

public comment on these proposed payment indicators and the payment rates for the new Category III CPT codes that were newly recognized as ASC covered ancillary services in July 2013 through the quarterly update CR, as listed in Table 35 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2014 OPPS/ASC final rule with comment period.

TABLE 35—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2013 AS ASC COVERED ANCILLARY SERVICES

CY 2013 CPT Code	CY 2013 Long descriptor	Proposed CY 2014 payment indicator	Proposed CY 2014 payment rate
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment	Z2	$212.08
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT.	Z2	212.08

3. Proposed Process for New Level II HCPCS Codes and Category I and III CPT Codes for Which We Will Be Soliciting Public Comments in the CY 2014 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and Category III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January ASC quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new codes in the final rule with comment period updating the ASC payment system for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addenda AA and BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update.

We are proposing to continue this process for CY 2014. Specifically, for CY 2014, we are proposing to include in Addenda AA and BB to the CY 2014 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2014, that would be incorporated in the January 2014 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2013 or January 1, 2014, that would be released by CMS in its October 2013 and January 2014 ASC quarterly update CRs. These codes would be flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2014 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim payment status. Their payment indicators and payment rates, if applicable, would be open to public comment in the CY 2014 OPPS/ASC final rule with comment period and would be finalized in the CY 2015 OPPS/ASC final rule with comment period.

C. Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Additions to the List of ASC Covered Surgical Procedures

We conducted a review of all HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Upon review, we did not identify any procedures that are currently excluded from the ASC list of procedures that met the definition of a covered surgical procedure based on our expectation that they would not pose a significant safety risk to Medicare beneficiaries or would require an overnight stay if performed in ASCs. Therefore, we are not proposing additions to the list of ASC covered surgical procedures for CY 2014.

b. Proposed Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated it would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of surgical procedures eligible for payment in ASCs, each year we identify surgical procedures as either temporarily office-based, permanently office-based, or non-office-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2014 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, we followed our policy to annually review and update the surgical procedures for which ASC payment is made and to identify new procedures that may be

appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2012 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator ''G2'' (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2013, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2*,'' ''P3*,'' or ''R2*'' in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68444 through 68448).

Our review of the CY 2012 volume and utilization data resulted in our identification of three covered surgical procedures that we believe meet the criteria for designation as office-based. The data indicate that the procedures are performed more than 50 percent of the time in physicians' offices, and our medical advisors believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The three CPT codes we are proposing to permanently designate as office-based are listed in Table 36 below.

TABLE 36—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR PERMANENT OFFICE-BASED DESIGNATION FOR CY 2014

CY 2013 CPT Code	CY 2013 Long descriptor	CY 2013 ASC Payment indicator	Proposed CY 2014 ASC payment indicator*
26341	Manipulation, palmar fascial cord (ie, dupuytren's cord), post enzyme injection (eg, collagenase), single cord.	G2	P3
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	G2	R2
36595	Mechanical removal of pericatheter obstructive material (eg, fibrin sheath) from central venous device via separate venous access.	G2	P3

*Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. According to the statutory formula, current law requires a negative update to the MPFS payment rates for CY 2014. For a discussion of those rates, we refer readers to the CY 2014 MPFS proposed rule.

We invite public comment on this proposal.

We also reviewed CY 2012 volume and utilization data and other information for the eight procedures finalized for temporary office-based status in Table 51 and Table 53 in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68442, 68446 through 68448). Among these eight procedures, there were very few claims data for four procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0124T (Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)); CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we are proposing to maintain their temporary office-based designations for CY 2014.

The volume and utilization data for one procedure that has a temporary office-based designation for CY 2013, CPT code 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)), is sufficient to indicate that this procedure is not performed predominantly in physicians' offices and, therefore, should not be assigned an office-based payment indicator in CY 2014. Consequently, we are proposing to assign payment indicator ''G2'' to this covered surgical procedure code in CY 2014.

The three remaining procedures that have temporary office-based designations for CY 2013 are proposed to be packaged under the OPPS for CY 2014 as discussed in section II.A.3. of this proposed rule. Consequently, we are proposing the assign payment indicator ''N1'' to the following three covered surgical procedure codes in CY 2014:

- CPT code 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed);
- CPT code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound); and
- CPT code 0300T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (list separately in addition to code for primary procedure)).

The proposed CY 2014 payment indicator designations for the eight procedures that were temporarily designated as office-based in CY 2013 are displayed in Table 37 below. The procedures for which the proposed office-based designations for CY 2014 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 37—PROPOSED CY 2014 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2013 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2013 CPT Code	CY 2013 Long descriptor	CY 2013 ASC payment indicator	Proposed CY 2014 ASC payment indicator**
0099T	Implantation of intrastromal corneal ring segments	R2*	R2*

TABLE 37—PROPOSED CY 2014 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2013 OPPS/ASC FINAL RULE WITH COMMENT PERIOD—Continued

CY 2013 CPT Code	CY 2013 Long descriptor	CY 2013 ASC payment indicator	Proposed CY 2014 ASC payment indicator**
0124T	Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication).	R2*	R2*
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed.	R2*	N1
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)	R2*	G2
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2*	N1
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (list separately in addition to code for primary procedure).	R2*	N1
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	R2*	R2*
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy.	R2*	R2*

* If designation is temporary.
** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. According to the statutory formula, current law requires a negative update to the MPFS payment rates for CY 2014. For a discussion of those rates, we refer readers to the CY 2014 MPFS proposed rule.

We invite public comment on this proposal.

c. ASC Covered Surgical Procedures Proposed to be Designated as Device-Intensive

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures.

(2) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2014

As discussed in section II.A.2.e of this proposed rule, for CY 2014, we are proposing to create 29 comprehensive APCs to replace 29 of the most costly device-dependent APCs under the OPPS. We are proposing to define a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, our OPPS proposal is to make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We are proposing to apply our standard APC ratesetting methodology to the remaining 10 device-dependent APCs to calculate their CY 2014 OPPS payment rates.

Unlike the OPPS claims processing system that can be configured to make a single payment for the encounter-based comprehensive service whenever a HCPCS code that is assigned to a comprehensive APC appears on the claim, the ASC claims processing system does not allow for this type of conditional packaging. Therefore, we are proposing that all separately paid ancillary services that are provided integral to surgical procedures that map to comprehensive APCs would continue to be separately paid under the ASC payment system instead of being packaged into the payment for the comprehensive APC as under the OPPS. In addition, to avoid duplicate payment for separately paid ancillary services provided integral to the surgical procedure because the OPPS relative weights for comprehensive APCs include costs for ancillary services, we are proposing that the ASC payment rates and device offset amounts for comprehensive APCs would be based on the CY 2014 OPPS relative payments weights that have been calculated using the standard APC ratesetting methodology instead of the relative payment weights that are based on the comprehensive service.

Payment rates for ASC device-intensive procedures are based on a modified payment methodology to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. Device-intensive procedures are currently defined as those procedures that are assigned to device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS. Because we are proposing to create comprehensive APCs to replace 29 of the 39 device-dependent APCs under the OPPS, we are proposing to define ASC device-intensive procedures as those procedures that are assigned to any APC with a device offset percentage greater than 50 percent based on the standard OPPS APC ratesetting methodology. We are proposing changes to § 416.171(b)(2) to reflect this proposal.

We also are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with this modified definition of device-intensive procedures, reflecting the proposed APC assignments of procedures and APC device offset percentages based on the CY 2012 OPPS claims and cost report data available for the proposed rule.

The ASC covered surgical procedures that we are proposing to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2014 are listed in Table 38 below. The CPT code, the CPT code short descriptor, the proposed CY 2014 ASC

payment indicator (PI), the proposed CY 2014 OPPS APC assignment, the proposed CY 2014 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply are also listed in Table 38 below. All of these procedures are included in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We invite public comment on this proposal.

d. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC policy with regard to payment for costly devices implanted in ASCs at no cost/full credit or partial credit as set forth in § 416.179 is consistent with the current OPPS policy. The established ASC policy adopts the OPPS policy and reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68744).

As discussed in section IV.B. of this proposed rule, we are proposing to modify our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Currently under the OPPS, our policy is to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we are proposing to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced device.

Although we are proposing to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, we are proposing to maintain our current ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual amount received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we are proposing to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively. We also are proposing to update the list of ASC covered device-intensive procedures that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2014. Table 38 below displays the ASC covered device-intensive procedures that we are proposing would be subject to the no cost/full credit or partial credit device adjustment policy for CY 2014. Specifically, when a procedure that is listed in Table 38 is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost to the ASC or with full credit. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

For partial credit, we are proposing to reduce the payment for implantation procedures listed in Table 38 that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more of the cost of the new device. The ASC would append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in Table 38 that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more of the cost of a device. In order to report that they received a partial credit of 50 percent or more of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more of the cost of the replacement device. Beneficiary coinsurance would continue to be based on the reduced payment amount.

TABLE 38—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2014, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH WE PROPOSE THAT THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

CPT Code	Short descriptor	Proposed CY 2014 ASC PI	Proposed CY 2014 OPPS APC	Proposed CY 2014 device-dependent APC offset percent	Proposing that FB/FC policy will apply
24361	Reconstruct elbow joint	J8	0425	59	Yes.
24363	Replace elbow joint	J8	0425	59	Yes.
24366	Reconstruct head of radius	J8	0425	59	Yes.
24370	Revise reconst elbow joint	J8	0425	59	Yes.
24371	Revise reconst elbow joint	J8	0425	59	Yes.
25441	Reconstruct wrist joint	J8	0425	59	Yes.
25442	Reconstruct wrist joint	J8	0425	59	Yes.
25446	Wrist replacement	J8	0425	59	Yes.

TABLE 38—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2014, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH WE PROPOSE THAT THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

CPT Code	Short descriptor	Proposed CY 2014 ASC PI	Proposed CY 2014 OPPS APC	Proposed CY 2014 device-dependent APC offset percent	Proposing that FB/FC policy will apply
27446	Revision of knee joint	J8	0425	59	Yes.
33206	Insert heart pm atrial	J8	0089	68	Yes.
33207	Insert heart pm ventricular	J8	0089	68	Yes.
33208	Insrt heart pm atrial & vent	J8	0655	72	Yes.
33212	Insert pulse gen sngl lead	J8	0090	67	Yes.
33213	Insert pulse gen dual leads	J8	0654	69	Yes.
33214	Upgrade of pacemaker system	J8	0655	72	Yes.
33221	Insert pulse gen mult leads	J8	0654	69	Yes.
33224	Insert pacing lead & connect	J8	0655	72	Yes.
33227	Remove&replace pm gen singl	J8	0090	67	Yes.
33228	Remv&replc pm gen dual lead	J8	0654	69	Yes.
33229	Remv&replc pm gen mult leads	J8	0654	69	Yes.
33230	Insrt pulse gen w/dual leads	J8	0107	80	Yes.
33231	Insrt pulse gen w/mult leads	J8	0107	80	Yes.
33240	Insrt pulse gen w/singl lead	J8	0107	80	Yes.
33249	Nsert pace-defib w/lead	J8	0108	82	Yes.
33262	Remv&replc cvd gen sing lead	J8	0107	80	Yes.
33263	Remv&replc cvd gen dual lead	J8	0107	80	Yes.
33264	Remv&replc cvd gen mult lead	J8	0107	80	Yes.
33282	Implant pat-active ht record	J8	0680	74	Yes.
37227	Fem/popl revasc stnt & ather	J8	0319	52	No
37231	Tib/per revasc stent & ather	J8	0319	52	No
53440	Male sling procedure	J8	0385	63	Yes.
53444	Insert tandem cuff	J8	0385	63	Yes.
53445	Insert uro/ves nck sphincter	J8	0386	70	Yes.
53447	Remove/replace ur sphincter	J8	0386	70	Yes.
54400	Insert semi-rigid prosthesis	J8	0385	63	Yes.
54401	Insert self-contd prosthesis	J8	0386	70	Yes.
54405	Insert multi-comp penis pros	J8	0386	70	Yes.
54410	Remove/replace penis prosth	J8	0386	70	Yes.
54416	Remv/repl penis contain pros	J8	0386	70	Yes.
55873	Cryoablate prostate	J8	0674	55	No
61885	Insrt/redo neurostim 1 array	J8	0039	86	Yes.
61886	Implant neurostim arrays	J8	0315	88	Yes.
62361	Implant spine infusion pump	J8	0227	81	Yes.
62362	Implant spine infusion pump	J8	0227	81	Yes.
63650	Implant neuroelectrodes	J8	0040	54	Yes.
63655	Implant neuroelectrodes	J8	0061	65	Yes.
63663	Revise spine eltrd perq aray	J8	0040	54	Yes.
63664	Revise spine eltrd plate	J8	0040	54	Yes.
63685	Insrt/redo spine n generator	J8	0039	86	Yes.
64553	Implant neuroelectrodes	J8	0040	54	Yes.
64555	Implant neuroelectrodes	J8	0040	54	Yes.
64561	Implant neuroelectrodes	J8	0040	54	Yes.
64565	Implant neuroelectrodes	J8	0040	54	Yes.
64568	Inc for vagus n elect impl	J8	0318	87	Yes.
64569	Revise/repl vagus n eltrd	J8	0040	54	Yes.
64575	Implant neuroelectrodes	J8	0061	65	Yes.
64580	Implant neuroelectrodes	J8	0061	65	Yes.
64581	Implant neuroelectrodes	J8	0061	65	Yes.
64590	Insrt/redo pn/gastr stimul	J8	0039	86	Yes.
65770	Revise cornea with implant	J8	0293	64	No
69714	Implant temple bone w/stimul	J8	0425	59	Yes.
69715	Temple bne implnt w/stimulat	J8	0425	59	Yes.
69717	Temple bone implant revision	J8	0425	59	Yes.
69718	Revise temple bone implant	J8	0425	59	Yes.
69930	Implant cochlear device	J8	0259	84	Yes.
0282T	Periph field stimul trial	J8	0040	54	Yes.
0283T	Periph field stimul perm	J8	0318	87	Yes.
0308T	Insj ocular telescope prosth	J8	0351	85	Yes.
0316T	Replc vagus nerve pls gen	J8	0039	86	Yes.
0319T	Insert subq defib w/eltrd	J8	0107	80	Yes.
0321T	Insert subq defib pls gen	J8	0107	80	Yes.

We invite public comment on these proposals.

e. ASC Treatment of Surgical Procedures Proposed for Removal From the OPPS Inpatient List for CY 2014

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. There are no procedures proposed for removal from the OPPS inpatient list for CY 2014, so we are not proposing any procedures for possible inclusion on the ASC list of covered surgical procedures under this section.

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2014 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary items and services because of changes that are being proposed under the OPPS for CY 2014. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2013 may be proposed for packaged status under the CY 2014 OPPS and, therefore, also under the ASC payment system for CY 2014. More specifically, as discussed in section II.A.3 of this proposed rule, we are proposing to package the following categories of ancillary or adjunctive services under the OPPS for CY 2014: drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; drugs and biologicals that function as supplies or devices when used in a surgical procedure; clinical diagnostic laboratory tests; procedures described by add-on codes; ancillary services (status indicator ''X''); diagnostic tests on the bypass list; and device removal procedures.

To maintain consistency with the OPPS, we are proposing that these services would be also packaged under the ASC payment system for CY 2014. Comment indicator ''CH,'' discussed in section XII.F. of the this proposed rule, is used in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2014.

Except for the Level II HCPCS codes and Level III CPT codes listed in Table 34 and Table 35 of this proposed rule, all ASC covered ancillary services and their proposed payment indicators for CY 2014 are included in Addendum BB to this proposed rule.

We invite public comment on this proposal.

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year is used to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2.'' Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and were, therefore, subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68434 through 68467), we updated the CY 2012 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2,'' ''G2,'' and ''J8'' using CY 2011 data, consistent with the CY 2013 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2013 OPPS device offset percentages.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2014 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2013 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2013 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2013 payment rate for the procedure according to the final policy of the revised ASC payment system (§ 416.171(d)).

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2014

We are proposing to update ASC payment rates for CY 2014 using the established rate calculation methodologies under § 416.171 and using our proposed modified definition for device-intensive procedures as discussed above. Because the proposed OPPS relative payment weights are based on geometric mean costs for CY 2014, the ASC system will use geometric means to determine proposed relative payment weights under the ASC standard methodology. We are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We are proposing that payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures (payment indicator ''J8'') be calculated according to our established policies, incorporating the device-intensive procedure methodology as appropriate. Thus, we are proposing to update the payment amounts for device-intensive procedures, using our proposed modified definition of device intensive procedures, based on the CY 2014 OPPS device offset percentages that have been calculated using the standard APC ratesetting methodology, and to make payment for office-based procedures at the lesser of the proposed CY 2014 MPFS nonfacility PE RVU-based amount or the proposed CY 2014 ASC payment amount calculated according to the standard ratesetting methodology.

We invite public comment on these proposals.

c. Waiver of Coinsurance and Deductible for Certain Preventive Services

Section 1833(a)(1) and section 1833(b)(1) of the Act waive the coinsurance and the Part B deductible for those preventive services under section 1861(ddd)(3)(A) of the Act as described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. Section 1833(b) of the Act also waives the Part B deductible for colorectal cancer screening tests that become diagnostic. In the CY 2011 OPPS/ASC final rule with comment period, we finalized our policies with respect to these provisions and identified the ASC covered surgical procedures and covered ancillary services that are preventive services that are recommended by the USPSTF with a grade of A or B for which the coinsurance and the deductible are waived. For a complete discussion of our policies and categories of services, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72047 through 72049). We are not proposing any changes to our policies or the categories of services for CY 2014. We identify the specific services with a double asterisk in Addenda AA and BB to this proposed rule.

d. Proposed Payment for Cardiac Resynchronization Therapy Services

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as ''CRT–D.'' In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2012 ASC payment rate for CRT–D services based on the OPPS payment rate applicable to APC 0108 when procedures described by CPT codes 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (list separately in addition to code for primary procedure)) and 33249 (Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber) are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service. For a complete discussion of our policy regarding payment for CRT–D services in ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74427 through 74428). For CY 2014, CPT code 33249, the primary code for CRT–D services, is proposed for continued assignment to APC 0108 but CPT code 33225 is proposed to be packaged under the OPPS.

Consequently, we are proposing that CPT code 33225 would also be packaged under the ASC payment system for CY 2014. Because CPT code 33225 is proposed to be packaged under the ASC payment system and, therefore, would not receive separate payment, it would no longer be necessary that ASCs use the HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service. Therefore, we are proposing that the ASC payment rate for CRT–D services (procedures described by CPT codes 33249 and 33225) would be based on the OPPS relative payment weight for APC 0108 for CY 2014 and that ASCs would no longer be required to assign HCPCS code G0448 when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service.

We invite public comment on these proposals.

e. Payment for Low Dose Rate (LDR) Prostate Brachytherapy Composite

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy); and CPT code 77778 (Interstitial radiation source application; complex). Generally, the component services represented by both codes are provided in the same operative session on the same date of service to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2013 ASC payment rate for LDR prostate brachytherapy services based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0458) for proper reporting when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service, and therefore receive the appropriate LDR prostate brachytherapy composite payment. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will continue to be assigned to APC 0651. When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will continue to be assigned to APC 0163. For a complete discussion of our policy regarding payment for LDR prostate brachytherapy services in ASCs, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68457). We are not proposing any changes to our current policy regarding ASC payment for LDR prostate brachytherapy services for CY 2014.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N,'' ''Q1,'' and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC proposed rule (77 FR 45169), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a

significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indictor ''N1'') under the ASC payment system. Thus, our final policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates. We generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower. This modification to the ASC payment methodology for ancillary services was finalized in response to a comment on the CY 2011 OPPS/ASC proposed rule that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, although packaged under the ASC payment system, is separately paid under the MPFS (42 CFR 416.171(d)(1)). We set the payment indicator to ''Z2'' for these nuclear medicine procedures in the ASC setting so that payment for these procedures would be based on the OPPS relative payment weight rather than the MPFS nonfacility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

In addition, because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MPFS), we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430) to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent (42 CFR 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Other separately paid covered ancillary services in ASCs, specifically corneal tissue acquisition and device categories with OPPS pass-through status, do not have prospectively established ASC payment rates according to the final policies of the revised ASC payment system (72 FR 42502 and 42508 through 42509; 42 CFR 416.164(b)). Under the revised ASC payment system, corneal tissue acquisition is paid based on the invoiced costs for acquiring the corneal tissue for transplantation. Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system. Currently, the three devices that are eligible for pass-through payment in the OPPS are described by HCPCS code C1830 (Powered bone marrow biopsy needle), HCPCS code C1840 (Lens, intraocular (telescopic)), and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)). Payment amounts for HCPCS codes C1830, C1840, and C1886 under the ASC payment system are contractor priced. In the CY 2013 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for HCPCS codes C1830, C1840, and C1886, which will expire after December 31, 2013 (77 FR 68353). Therefore, after December 31, 2013, the costs for devices described by HCPCS codes C1830, C1840, and C1886, will be packaged into the costs of the procedures with which the devices are reported in the hospital claims data used in the development of the OPPS relative payment weights that will be used to establish ASC payment rates for CY 2014.

b. Proposed Payment for Covered Ancillary Services for CY 2014

For CY 2014, we are proposing to update the ASC payment rates and make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2014 OPPS and ASC payment rates. The proposed CY 2014 OPPS payment methodologies for brachytherapy sources and separately payable drugs and biologicals are discussed in section II.A. and section V.B. of this proposed rule, respectively, and we are proposing to set the CY 2014 ASC payment rates for those services equal to the proposed CY 2014 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2014 payment for separately payable covered radiology services is based on a comparison of the CY 2014 proposed MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2014 MPFS proposed rule) and the proposed CY 2014 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). Alternatively, payment for a radiology service may be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally packaged under the OPPS. The payment indicators in Addendum BB to this proposed rule indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology, or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator ''N1''). Radiology services that we are proposing to pay based on the ASC standard ratesetting methodology are assigned payment indicator ''Z2'' (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight) and those for which the proposed payment is based on the MPFS nonfacility PE RVU-based amount are assigned payment indicator ''Z3'' (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs).

As finalized in the CY 2011 OPPS/ASC final rule with comment period (75

FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment for these procedures will be based on the OPPS relative payment weight (rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower) and, therefore, will include the cost for the diagnostic radiopharmaceutical. We are proposing to continue this modification to the payment methodology in CY 2014 and, therefore, set the payment indicator to ''Z2'' for nuclear medicine procedures.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), payment indicators for radiology services that use contrast agents are set to ''Z2'' so that payment for these procedures will be based on the OPPS relative payment weight and, therefore, will include the cost for the contrast agent. We are proposing to continue this modification to the payment methodology in CY 2014 and, therefore, set the payment indicator to ''Z2'' for radiology services that use contrast agents.

Most covered ancillary services and their proposed payment indicators are listed in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site). We invite public comment on these proposals.

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of new technology intraocular lenses (NTIOLs) is as follows:

- Applicants submit their NTIOL requests for review to CMS by the deadline. For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an existing NTIOL Class'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.
- We announce annually in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—
  - Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments;
  - When a new NTIOL class is created, we identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.
  - The date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class would be set prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.
  - Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2014

We did not receive any requests for review to establish a new NTIOL class for CY 2014 by the March 1, 2013, the due date published in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68461).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2014.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we also created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' is also assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2014 OPPS/ASC final rule with comment period, we will respond to public comments and finalize the ASC treatment of all codes that are labeled with comment indicator ''NI'' in Addenda AA and BB to the CY 2013 OPPS/ASC final rule with comment period.

The ''CH'' comment indicator is used in Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code in current year and next calendar year; an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. Proposed ASC Payment and Comment Indicators

We are not proposing any changes to the definitions of the ASC payment and comment indicators for CY 2014. We refer readers to Addenda DD1 and DD2 to this proposed rule (which are available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2014 update.

G. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007 as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures and covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2.b. of this proposed rule), the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage indices to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003. The reclassification provision provided at section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available raw pre-floor and pre-reclassified hospital wage indices results in the most appropriate adjustment to the labor portion of ASC costs. In addition, use of the unadjusted hospital wage data avoids further reductions in certain rural statewide wage index values that result from reclassification. We continue to believe that the unadjusted hospital wage indices, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs.

We note that in certain instances there might be urban or rural areas for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indices for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). We have applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72058 through 72059), we finalized our proposal to set the ASC wage index by calculating the average of all wage indices for urban areas in the State when all contiguous areas to a CBSA are rural and there is no IPPS hospital whose wage index data could be used to set the wage index for that area. In other situations, where there are no IPPS hospitals located in a relevant labor market area, we will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indices for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2014 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). Consistent with our established policy, we are proposing to scale the CY 2014 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2012, we are

proposing to compare the total payment using the CY 2013 ASC relative payment weights with the total payment using the CY 2014 relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2013 and CY 2014. We are proposing to use the ratio of CY 2013 to CY 2014 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2014. The proposed CY 2014 ASC scaler is 0.8961 and scaling would apply to the ASC relative payment weights of the covered surgical procedures and covered ancillary radiology services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We currently have available 98 percent of CY 2012 ASC claims data.

To create an analytic file to support calculation of the weight scaler and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2012 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2012 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html*.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2014 ASC payment system, we are proposing to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2014, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2012 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2014 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2012 ASC utilization and service-mix and the proposed CY 2014 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2013 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2014 pre-floor and pre-reclassified hospital wage indices. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2013 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2014 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0004 (the proposed CY 2014 ASC wage index budget neutrality adjustment) to the CY 2013 ASC conversion factor to calculate the proposed CY 2014 ASC conversion factor. We note that, on February 28, 2013, OMB issued OMB Bulletin No. 13–01 announcing revisions to the delineation of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The proposed pre-floor and pre-reclassified hospital wage indices for FY 2014 do not reflect OMB's new area delineations. Because the ASC wage indices are the pre-floor and pre-reclassified hospital wage indices, the FY 2014 ASC wage indices will not reflect the OMB changes.

Section 1833(i)(2)(C)(i) of the Act requires that, ''if the Secretary has not updated amounts established'' under the revised ASC payment system in a calendar year, the payment amounts ''shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.'' The statute, therefore, does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor).

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that ''any annual update under [the ASC payment] system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)'' of the Act effective with the calendar year beginning January 1, 2011. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASCQR Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for the CY 2014 payment determination and subsequent years.

The application of the 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We amended §§ 416.160(a)(1) and 416.171 to reflect these policies.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the ''percentage increase'' in the CPI–U, which we interpret cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI–U for a year is negative, we would hold the CPI–U update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the rules established by the Secretary in accordance with section 1833(i)(7) of the Act. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction, by the MFP adjustment, and states that application of the MFP adjustment to the annual update factor after application of any quality reporting reduction may result in the update being less than zero for a year. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. Illustrative examples of how the MFP adjustment would be applied to the ASC payment system update are found in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064).

For this proposed rule, based on IHS Global Insight (IGI) 2013 first quarter forecast with historical data through 2012 fourth quarter, for the 12-month period ending with the midpoint of CY 2014, the CPI–U update is projected to be 1.4 percent. Also based on IGI's 2013 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2014 is projected to be 0.5 percent. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of CMS' market baskets as well as the CPI–U and MFP. The methodology for calculating the MFP adjustment was finalized in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) as revised in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301). Because the ASCQR Program affects payment rates beginning in CY 2014, there would be a 2.0 percentage point reduction to the CPI–U for ASCs that fail to meet the ASCQR Program requirements.

We are proposing to reduce the CPI–U update of 1.4 percent by the MFP adjustment of 0.5 percentage point, resulting in an MFP-adjusted CPI–U update factor of 0.9 percent for ASCs meeting the quality reporting requirements. Therefore, we are proposing to apply a 0.9 percent MFP-adjusted CPI–U update factor to the CY 2013 ASC conversion factor for ASCs meeting the quality reporting requirements. We are proposing to reduce the CPI–U update of 1.4 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then apply the 0.5 percentage point MFP reduction. Therefore, we are proposing to apply a −1.1 percent quality reporting/MFP-adjusted CPI–U update factor to the CY 2013 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the CY 2014 CPI–U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2014 ASC update for the final rule with comment period.

For CY 2014, we also are proposing to adjust the CY 2013 ASC conversion factor ($42.917) by the wage adjustment for budget neutrality of 1.0004 in addition to the MFP-adjusted update factor of 0.9 percent discussed above, which results in a proposed CY 2014 ASC conversion factor of $43.321 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are proposing to adjust the CY 2013 ASC conversion factor ($42.917) by the wage adjustment for budget neutrality of 1.0004 in addition to the quality reporting/MFP-adjusted update factor of −1.1 percent discussed above, which results in a proposed CY 2014 ASC conversion factor of $42.462.

We invite public comment on these proposals.

3. Display of Proposed CY 2014 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) display the proposed updated ASC payment rates for CY 2014 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the proposed CY 2014 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Subject to Multiple Procedure Discounting'' indicates that the surgical procedure will be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session. Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2014. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that the payment indicator assignment is an interim assignment that is open to comment in the final rule with comment period.

The values displayed in the column titled ''CY 2014 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2014. The payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Thus, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the proposed CY 2014 payment rate displayed in the ''CY 2014 Payment'' column, each ASC payment weight in the ''CY 2014 Payment Weight'' column was multiplied by the proposed CY 2014 conversion factor of $43.321. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as

discussed in section XII.H.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the ''CY 2014 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''CY 2014 Payment'' column displays the proposed CY 2014 national unadjusted ASC payment rates for all items and services. The proposed CY 2014 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in April 2013.

XIII. Hospital Outpatient Quality Reporting Program Updates

A. Background

1. Overview

CMS has implemented quality measure reporting programs for multiple settings of care. These programs promote higher quality, more efficient health care for Medicare beneficiaries. The quality data reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (Hospital OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), has been generally modeled after the quality data reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (Hospital IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). Both of these quality reporting programs for hospital services have financial incentives for the reporting of quality data to CMS.

CMS also has implemented quality measure reporting programs for other settings of care and for certain professionals, including:

- Care furnished by physicians and other eligible professionals, under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities, under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals, under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program;
- PPS-exempt cancer hospitals, under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers, under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities, under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program;
- Home health agencies, under the Home Health Quality Reporting Program (HH QRP); and
- Hospices, under the Hospice Quality Reporting Program.

Finally, CMS has implemented a Hospital Value-Based Purchasing Program and an end-stage renal disease (ESRD) Quality Incentive Program that link payment to performance.

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries as reflected in the National Quality Strategy, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. To the extent possible under various authorizing statutes, our ultimate goal is to align the clinical quality measure requirements of the Hospital OQR Program and various other programs, such as the Hospital IQR Program, the ASCQR Program, and the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, authorized by the Health Information Technology for Economic and Clinical Health Act, so that the burden for reporting will be reduced. As appropriate, we will consider the adoption of measures with electronic specifications, to enable the collection of this information as part of care delivery. Establishing such an alignment will require interoperability between EHRs, and CMS data collection systems, with data being calculated and submitted via certified EHR technology; additional infrastructural development on the part of hospitals and CMS; and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. Once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital OQR Program measure set with less cost and burden to hospitals.

In implementing this and other quality reporting programs, we generally applied the same principles for the development and the use of measures, with some differences that relate to the specific characteristics of each program:

- Our overarching goal is to support the National Quality Strategy's goal of better health care for individuals, better health for populations, and lower costs for health care. The Hospital OQR Program will help achieve these goals by creating transparency around the quality of care at hospital outpatient departments to support patient decision-making and quality improvement. Given the availability of well validated measures and the need to balance breadth with minimizing burden, measures should take into account and address, as fully as possible, the six domains of measurement that arise from the six priorities of the National Quality Strategy: Clinical care; Person- and caregiver-centered experience and outcomes; Safety; Efficiency and cost reduction; Care coordination; and Community/population health. More information regarding the National Quality Strategy can be found at: *http://www.healthcare.gov/law/resources/reports/*. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.
- Pay-for-reporting and public reporting should rely on a mix of structural, processes, outcomes, efficiency, and patient experience of care measures, including measures of care transitions and changes in patient functional status.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare and Medicaid public reporting and incentive payment systems to promote coordinated efforts to improve quality. The measure sets should evolve so that they include a focused set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider category.
- We weigh the relevance and the utility of measures compared to the burden on hospitals in submitting data under the Hospital OQR Program. The collection of information burden on providers should be minimized to the extent possible. To this end, we are working toward the eventual adoption of electronically-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden. We also seek to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims databases. In recent years we have adopted measures that do not require chart abstraction, including structural measures and claims-based measures

that we can calculate using other data sources.

- To the extent practicable and feasible, and recognizing differences in statutory authorities, measures used by CMS should be endorsed by a national, multi-stakeholder organization.
- We take into account the views of multi-stakeholder groups. Section 3014 of the Affordable Care Act added section 1890A of the Act, establishing a pre-rulemaking process, which, among other steps, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting certain categories of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. As part of the pre-rulemaking process, the consensus-based entity that CMS must contract with under section 1890 of the Act (currently the National Quality Forum (NQF)), convened the multi-stakeholder groups referred to as the Measure Applications Partnership (MAP). The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of the categories of measures in section 1890(B)(7)(B) of the Act, which include measures for use in certain specific Medicare programs, measures for use in reporting performance information to the public, and measures for use in health care programs other than for use under the Act. Information about the MAP can be found at *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.*
- Measures should be developed with the input of providers, purchasers/payers, consumers, and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.
- HHS Strategic Plan and Initiatives. HHS is the U.S. government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The goals of the HHS Strategic Plan for Fiscal Years 2010 through 2015 are to: Transform Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (*http://www.hhs.gov/about/FY2012budget/strategicplandetail.pdf*). HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce Healthcare-associated Infections (HAIs) in clinical settings and the Partnership for Patients exemplify these programs.
- CMS strives to ensure that quality measures for the Medicare, Medicaid, and the Children's Health Insurance Programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used, and that quality measures are collected from EHRs as appropriate. Quality goals are embedded in the CMS Strategy.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74451 through 74452), we responded to public comment on many of these principles. In the CY 2013 OPPS/ASC final rulemaking (77 FR 68467 through 68469), with a few minor differences, we generally applied the same principles for our considerations for future measures.

2. Statutory History of the Hospital Outpatient Quality Reporting (Hospital OQR) Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Measure Updates and Data Publication

a. Process for Updating Quality Measures

Technical specifications for the Hospital OQR Program measures are listed in the Hospital OQR Specifications Manual, which is posted on the CMS QualityNet Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228772438492.*

We maintain the technical specifications for the measures by updating this Hospital OQR Specifications Manual and including detailed instructions and calculation algorithms. In some cases where the specifications are available elsewhere, we may include links to Web sites hosting technical specifications. These resources are for hospitals to use when collecting and submitting data on required measures.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established an additional subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. We believe that a measure can be updated through this subregulatory process provided it is a nonsubstantive change. We expect to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis.

Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that non-substantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. We will revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. As stated in CY 2009 OPPS/ASC, we also will post the updates on the QualityNet Web site at *https://www.QualityNet.org.* We will provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary. We generally release the Hospital OQR Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for nonsubstantive changes such as changes to ICD–9, CPT, NUBC, and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the OQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example: changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice.

We believe that the policy finalized in the CY 2009 OPPS/ASC final rule adequately balances our need to incorporate non-substantive NQF updates to NQF-endorsed Hospital OQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. These policies regarding what is considered substantive versus non-substantive apply to all measures in the Hospital OQR Program.

b. Publication of Hospital OQR Program Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public, with respect to the hospital prior to such data being made public. To meet these requirements, data that a hospital has submitted for the Hospital OQR Program are typically provided to hospitals for a preview period via QualityNet, and then are usually displayed on our *Hospital Compare* Web site, *http://www.hospitalcompare.medicare.gov,* following the preview period, although we might use other Web sites, as discussed below. The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care. We believe this information motivates beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thus providing additional incentives to hospitals to improve the quality of care that they furnish.

Under our current policy, we publish quality data by the corresponding hospital CMS Certification Number (CCN), and indicate instances where data from two or more hospitals are combined to form the publicly reported measures on the *Hospital Compare* Web site. That is, in a situation in which a larger hospital has taken over ownership of a smaller hospital, the smaller hospital's CCN will be replaced by the larger hospital's CCN (the principal CCN). For data display purposes, we will only display data received under the principal CCN. If both hospitals are submitting data, those data are not distinguishable in the warehouse; and the data is calculated together as one hospital.

Consistent with our current policy, we make Hospital IQR and Hospital OQR data publicly available whether or not the data have been validated for payment purposes. The *Hospital Compare* Web site currently displays information covering process of care measures, outcome of care measures, outpatient imaging efficiency measures and HCAHPS data.

In general, we strive to display hospital quality measure data on the *Hospital Compare* Web site as soon as possible after measure data have been submitted to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other CMS Web sites such as: *http://www.cms.hhs.gov/HospitalQualityInits/* or *https://data.medicare.gov/*. Publicly reporting the information in this manner, although not on the *Hospital Compare* Web site, allows us to meet the requirement under section 1833(t)(17)(E) of the Act for establishing procedures to make quality data submitted available to the public following a preview period. When we display hospital quality information on non-interactive CMS Web sites, affected parties will be notified via CMS listservs, CMS email blasts, memoranda, Hospital Open Door Forums, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare.*

We also require hospitals to complete and submit an online registration form (''participation form'') in order to participate in the Hospital OQR Program. With submission of this participation form, participating hospitals agree that they will allow CMS to publicly report the quality measure data submitted under the Hospital OQR Program, including measures that we calculate using Medicare claims.

B. Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471), for the purpose of streamlining the rulemaking process, we finalized a policy that, beginning with the CY 2013 rulemaking, when we adopt measures for the Hospital OQR Program beginning with a payment determination and subsequent years, these measures are automatically adopted for all subsequent years payment determinations unless we propose to remove, suspend, or replace the measures.

C. Removal or Suspension of Quality Measures From the Hospital OQR Program Measure Set

1. Considerations in Removing Quality Measures From the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS rulemaking, we finalized a process for immediate retirement of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raises patient safety concerns (74 FR 43864 through 43865). We adopted this same immediate measure retirement policy for the Hospital OQR Program in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634).

In previous Hospital IQR Program rulemakings, we have referred to the removal of measures from the Hospital IQR Program as ''retirement.'' We have used this term to indicate that Hospital IQR Program measures are no longer included in the Hospital IQR Program measure set for one or more indicated reasons. However, we note that this term may imply that other payers/purchasers/programs should cease using these measures that are no longer required for the Hospital IQR Program. In order to clarify that this is not our intent, we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53506 through 53507) that we will use the term ''remove'' rather than ''retire'' to refer to the action of no longer including a measure in the Hospital IQR Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473), we adopted the same terminology of ''removal'' in the Hospital OQR Program to indicate our action of discontinuing a measure in the Hospital OQR Program.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), we finalized a set of criteria to use when determining whether to remove Hospital OQR Program measures. These criteria are: (1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures); (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient

outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences such as patient harm. These criteria were suggested by commenters during Hospital IQR Program rulemaking, and we determined that these criteria are also applicable in evaluating Hospital OQR Program quality measures for removal. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473), we finalized our proposal to apply these measure removal criteria in the Hospital OQR Program as well.

In addition to these criteria, we take into account the views of the MAP in the evaluation of measure removal. Furthermore, for efficiency and streamlining purposes, we strive to eliminate redundancy of similar measures.

2. Proposed Removal of Two Chart-Abstracted Measures From the Hospital OQR Program

In this rulemaking, we are proposing to remove two measures from the Hospital OQR Program for the CY 2016 payment determination and subsequent years: (1) OP–19: Transition Record with Specified Elements Received by Discharged ED Patients and (2) OP–24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting. The rationales for these proposals are discussed below.

a. Proposed Removal of OP–19: Transition Record With Specified Elements Received by Discharged ED Patients

We previously adopted measure OP–19 for the Hospital OQR Program for the CY 2013 payment determination with data collection beginning with January 1, 2012 encounters in the CY 2011 OPPS/ASC final rule with comment period. Shortly after data collection for this measure began in January 2012, hospitals raised concerns about the measure specifications, including potential privacy issues related to releasing certain elements of the transition record to either the patient being discharged from an emergency department or the patient's caregiver. Some examples provided by hospitals are the release of sensitive lab results or radiological findings to a parent, spouse, or guardian of a minor patient, or to the responsible party for a physically incapacitated patient.

In order to address the safety concerns related to confidentiality as raised by the industry in the above discussion, in April 2012, we took immediate action to suspend OP–19. On April 12, 2012, we released a Memorandum entitled SDPS 12–100–OD, ''Revised: Temporary Suspension of Hospital Outpatient Quality Reporting Measure OP–19: Transition Record with Specified Elements Received by Discharged Patients'' to make clear our intent not to use any data submitted on this measure for payment determinations, public reporting, or data validation. This memorandum can be located at *http://qualitynet.org*) under the option ''Email Notifications'' within the ''Hospitals—Outpatient'' drop down menu found at the top of the page.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68474 through 68476) for the CY 2014 payment determination and subsequent years, we confirmed that we suspended the collection of data for the measure OP–19: Transition Record with Specified Elements Received by Discharged ED Patients, which specified that either patients *or their caregivers* (emphasis added) receive a transition record at the time of ED discharge.

We chose to suspend this measure rather than to immediately remove the measure from the program because the probability of harm occurring was relatively low; any potential harm that occurred would not be the direct result of patient care rendered at facilities; and the measure steward, the American Medical Association Physician Consortium for Performance Improvement (AMA–PCPI), believed that the measure could be quickly re-specified in a manner that would mitigate the concerns raised by hospitals and stakeholders. In the CY 2013 OPPS/ASC final rule with comment period, we noted that the measure steward was working to revise the measure specifications to address the concerns raised by affected parties. We also noted that the measure was scheduled for NQF maintenance review in 2013. We stated that after completion of the NQF maintenance process, we anticipated that normal program operations for this measure could resume once we updated the Hospital OQR Specifications Manual and made any necessary changes to our data collection infrastructure. In addition, we stated that we would notify hospitals of changes in the suspension status of the measure for the Hospital OQR Program via email blast. However, we indicated that if we determined that these concerns cannot be adequately addressed by measure specifications, we would propose to remove this measure in a future OPPS/ASC rule.

We have determined that the measure cannot be implemented with the degree of specificity that would be needed to fully address the concerns of stakeholders without being overly burdensome. The measure steward resolved the safety issue by refining the measure, but the refinement has made data abstraction more subjective because individual hospitals can determine which information should be included in the transition record in order to comply with this measure. In the absence of standardized data elements, we were not able to resolve this issue of data abstraction for common data elements, and therefore, could not ensure consistency of data submission and accuracy of measure results.

We also learned that all aspects for this transition record measure are currently required to meet the Medicare EHR Incentive Program's meaningful use (MU) core objective for eligible hospitals and critical access hospitals (CAHs) to provide patients the ability to view online, download, and transmit information about a hospital admission. This MU core objective provides patients discharged from the inpatient department or Emergency Department (ED) online access to their visit data. These ED visit data are the specified data elements included in the OP–19 Transition Record measure. This means that if we were to keep this measure, hospitals would need to submit this data for both the Hospital OQR Program using chart-abstraction and via attestation for the MU core objective. Therefore, to reduce duplicative requirements among programs and measurement burden, we are proposing to remove this measure from the Hospital OQR Program. We invite public comment on the proposed removal of this measure from the Hospital OQR Program.

b. Proposed Removal of OP–24: Cardiac Rehabilitation Measure: Patient Referral From an Outpatient Setting

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68476), we deferred data collection for this measure to January 1, 2014 encounters. This was due to the unavailability of detailed abstraction instructions for data collection in time for the July 2012 release of the Hospital OQR Specifications Manual which was needed for chart-abstraction beginning on January 1, 2013. We also indicated that this measure would be applied to the CY 2015 payment determination.

We are proposing to remove this measure from the Hospital OQR Program due to continued difficulties with defining the measure care setting.

The measure specifications provided by the measure steward, the American College of Cardiology (ACC), identify the applicable care setting as a 'Clinician Office/Clinic' and not as a hospital outpatient setting. In developing the specifications for this measure for a hospital outpatient setting, several issues arose. First, it is difficult to accurately identify the purpose of hospital outpatient visits, such as for evaluation and management purposes, using solely HOPD claims data. Second, it is difficult for hospitals to determine which particular clinic visit resulted in a cardiac rehabilitation referral for any given patient. Therefore, given the difficulties in accurately applying the measure to the hospital outpatient setting, we are proposing to remove OP–24 from the Hospital OQR Program. We invite public comment on this proposal to remove this measure from the Hospital OQR Program.

PROPOSED HOSPITAL OQR PROGRAM MEASURES TO BE REMOVED FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure
0649	OP–19: Transition Record with Specified Elements Received by Discharged ED Patients.
0643	OP–24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting.

D. Quality Measures Previously Adopted for the CY 2014 and CY 2015 Payment Determinations and Subsequent Years

The table below lists 25 measures that we previously adopted and retained for the CY 2014 and CY 2015 payment determinations and subsequent years under the Hospital OQR Program. This list includes measures we are proposing to remove in this proposed rule.

HOSPITAL OQR PROGRAM MEASURES FOR THE CY 2014 AND CY 2015 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS

NQF No.	Measure name
0287	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.
0289	OP–5: Median Time to ECG.
0270	OP–6: Timing of Antibiotic Prophylaxis.
0268	OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
	OP–9: Mammography Follow-up Rates.
	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
0489	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache. *
0491	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
0649	OP–19: Transition Record with Specified Elements Received by Discharged ED Patients.
	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
	OP–22: ED—Patient Left Without Being Seen.
0661	OP–23: ED—Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
0643	OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting.
	OP–25: Safe Surgery Checklist Use.
	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures. **

* Public reporting for OP–15 continues to be deferred at the time of this CY 2014 OPPS/ASC proposed rule.

** OP–26 Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v+6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs.*

E. Proposed Quality Measures for the CY 2016 Payment Determination and Subsequent Years

In this rulemaking, we are proposing to adopt five new measures for the Hospital OQR Program for the CY 2016 payment determination and subsequent years. These measures include one HAI measure—Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), currently collected by the Centers for Disease Control and Prevention (CDC) via the National Healthcare Safety Network (NHSN)—and four chart-abstracted measures. The chart-abstracted measures are: (1) Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564), (2) Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients (NQF #0658), (3) Endoscopy/Poly surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF

#0659), and (4) Cataracts: Improvement in Patient's Visional Function within 90 Days Following Cataract Surgery (NQF #1536).

The proposed measures were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2012'' on the NQF Web site at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx* in compliance with section 1890A(a)(2) of the Act. They were reviewed by the MAP in its ''MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS,'' which has been made available on the NQF Web site at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*. We considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital OQR Program.

All five of the proposed measures are NQF-endorsed, and therefore meet the requirements that measures selected for the program ''reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities'' under section 1833(t)(17)(C)(i) of the Act. Furthermore, the services targeted in the proposed measures are services commonly provided to patients who visit hospital outpatient departments and, for this reason, we believe that these proposed measures are appropriate for the measurement of quality of care furnished by hospitals in outpatient settings as required under section 1833(t)(17)(C)(i) of the Act.

We are proposing to collect aggregate data (numerators, denominators, exclusions) for the four chart-abstracted measures via an online, Web-based tool that will be made available to HOPDs via the QualityNet Web site, just as we do for OP–22. This Web-based tool is currently in use in the Hospital OQR Program to collect structural measure information.

More information regarding this proposed method of collection is provided in section XIII.H.2. of this proposed rule.

To enhance our efforts to collect high quality data for the Hospital OQR measures while minimizing burden for HOPDs, we also seek public comment on whether we should collect patient-level data via certified EHR technology on the four proposed measures excluding the Influenza Vaccination Coverage among Healthcare Personnel measure, and the potential timing for doing so. Collecting patient-level data, as we do for other Hospital OQR Program measures such as OP–1 through OP–7, would allow CMS to validate the accuracy of the data and also link data for patients over time to assess patient outcomes of care related to treatment.

The proposed measures are described in greater detail below.

1. Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

This proposed measure assesses the percentage of healthcare personnel (HCP) who have been immunized for influenza. Rates of serious illness and death resulting from influenza and its complications are increased in high-risk populations such as persons over 50 years or under four years of age, and persons of any age who have underlying conditions that put them at an increased risk. HCP can acquire influenza from patients and can transmit influenza to patients and other HCP. Many HCP provide care for, or are in frequent contact with, patients with influenza or patients at high risk for complications of influenza. The involvement of HCP in influenza transmission has been a long-standing concern.[1] [2] [3]

Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.[4] HCP are considered a high priority for expanding influenza vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and healthcare costs. Due to the significant impact of HCP influenza vaccination on patient outcomes, we believe this measure is appropriate for measuring the quality of care in hospital outpatient departments.

We are proposing to adopt this process measure for the CY 2016 payment determination and subsequent years. We are also proposing that Hospital OPDs use the NHSN infrastructure and protocol to report the measure for Hospital OQR program purposes. The measure numerator is: HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: (a) Received an influenza vaccination administered at the healthcare facility, or reported in writing (paper or electronic) or provided documentation that influenza vaccination was received elsewhere; (b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other component(s) of the vaccine, or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; (c) declined; or (d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories. The measure denominator is: the number of HCP who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the influenza season, regardless of clinical responsibility or patient contact. The specifications for this measure are available at *http://www.qualityforum.org/QPS/QPSTool.aspx?Exact=false&Keyword=0431*.

In its 2013 Pre-Rulemaking Report, (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), the MAP supported inclusion of this measure in the Hospital OQR Program and noted that the measure would address a measure type that is not adequately represented in the program measure set. Furthermore, the adoption of this measure will align with both the Hospital IQR Program, which adopted the measure for the FY 2015 payment determination and subsequent years, and the ASCQR Program, which adopted the measure for the CY 2016 payment determination and subsequent years.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42323 through 42324), we proposed this measure for the CY 2015 payment determination. However, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74470 through 74472), we decided not to finalize the measure (76 FR 74472) and, instead, decided to propose it in future rulemaking for the CY 2016 payment determination and subsequent years in order to address measure refinements in the denominator and operational issues. We believe that these refinements have been made and that the operational issues have been resolved.

We have learned that many States are proactively aligning their reporting requirements for this measure to mirror

[1] Maltezou, H.C., Drancourt, M.: Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83–91.

[2] Hurley, J.C., Flockhart, S.: An influenza outbreak in a regional residential facility. Journal of Infection Prevention 2010; 11:58–61.

[3] Salgado, C.D, Farr, B.M., Hall, K.K., Hayden, F.G.: Influenza in the acute hospital setting. The Lancet Infectious Diseases 2002; 2:145–155.

[4] Wilde, M.A., McMillan, J.A., Serwint, J., Butta, J., O'Riordan, M.A., Steinhoff, M.C.: Effectiveness of influenza vaccine in health care professionals; a randomized trial. The Journal of the American Medical Association 1999;281:908–913.

the federal requirements in an effort to reduce burden on providers and suppliers. We also recently learned that the measure may soon be undergoing some minor updates and review by NQF. Consistent with our policy to use a subregulatory process to adopt nonsubstantive changes to measures arising out of the NQF process (73 FR 68766 through 68767), we would use this process to adopt the upcoming NQF revisions for this measure, if the revisions are nonsubstantive.

We refer readers to section XIII.H.2. of this proposed rule for a detailed discussion of data collection. We invite public comment on this proposal.

2. Complications Within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564)

This proposed measure assesses the percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: Retained nuclear fragments, endophthalmitis, dislocated or wrong power intraocular lens (IOL), retinal detachment, or wound dehiscence.

Although complications that may result in a permanent loss of vision following cataract surgery are uncommon, this outcome measure seeks to identify those complications from surgery that can reasonably be attributed to the surgery. It focuses on patient safety and monitoring for events that, while uncommon, can signify important issues in the care being provided. Advances in technology and surgical skills over the last 30 years have rendered cataract surgery safer and more effective. An analysis of Managed Care Organization data demonstrated that the rate of complications for this measure were 1 to 2 percent. However, with an annual volume of 2.8 million cataract surgeries in the United States, many of which are performed in hospital surgical outpatient departments, a 2-percent rate is a significant number of surgeries associated with complications.[5]

The measure numerator is: Patients who had one or more specified operative procedures for any of the following major complications within 30 days following cataract surgery: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence. The measure denominator is: All patients aged 18 years and older who had cataract surgery and no significant pre-operative ocular conditions impacting the surgical complication rate. This measure excludes patients with certain comorbid conditions impacting the surgical complication rate. The specifications for this measure are available at *http://www.qualityforum.org/QPS/0564*.

In its 2013 Pre-Rulemaking Report, (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), the MAP supported this measure and noted that the measure addresses a high impact condition that is not adequately addressed in the Hospital OQR measure set. Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of this proposed rule for a detailed discussion of data collection. We invite public comment on this proposal.

3. Endoscopy/Poly Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)

This proposed measure assesses the percentage of patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.

In the average-risk population, colonoscopy screening is recommended in current guidelines at 10-year intervals.[6] Our analysis indicated that about 25 percent of surgeries/procedures performed in HOPDs and ASCs are colonoscopies. Performing colonoscopy too frequently increases patients' exposure to procedural harm. This measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years.

The measure numerator is: Patients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. The measure denominator is: all patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy. This measure excludes patients with documentation of medical reason(s) for recommending a follow-up interval of less than 10 years (for example, an above-average risk patient or inadequate prep). The specifications for this measure are available at: *http://www.qualityforum.org/QPS/0658*.

In its 2013 Pre-Rulemaking Report, (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), the MAP supported the direction of the measure. Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of this proposed rule for a detailed discussion of data collection. We invite public comment on this proposal.

4. Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients With a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659)

The proposed Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use measure assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report.

Colonoscopy is the recommended method of surveillance after the removal of adenomatous polyps, because it has been shown to significantly reduce subsequent colorectal cancer incidence. The timing of follow-up colonoscopy should be tailored to the number, size, and pathologic findings of the adenomatous polyps removed. A randomized trial of 699 patients showed that after newly diagnosed adenomatous polyps have been removed by colonoscopy, follow-up colonoscopy at 3 years detects important colonic lesions as effectively as follow-up colonoscopy at both 1 and 3 years.[7] [8]

[5] National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at *http://qualitymeasures.ahrq.gov/content.aspx?id=27981&search=complications+within+30+days+following+cataract+surgery*.

[6] Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. Gastrointest Endosc 2006 Apr;63(4):546–57. *http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract*.

[7] National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at *http://qualitymeasures.ahrq.gov/content.aspx?id=27981&search=complications+within+30+days+following+cataract+surgery*.

[8] Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA,

Continued

The measure numerator for this proposed measure is: Patients who had an interval of 3 or more years since their last colonoscopy. The measure denominator is: all patients aged 18 years and older receiving a surveillance colonoscopy with a history of a prior colonic polyp in a previous colonoscopy. This measure excludes patients with: (1) Documentation of medical reason(s) for an interval of less than 3 years since the last colonoscopy (for example, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas); or (2) documentation of a system reason(s) for an interval of less than 3 years since the last colonoscopy (for example, unable to locate previous colonoscopy report, previous colonoscopy report was incomplete). The specifications for this measure are available at *http://www.qualityforum.org/QPS/0659*.

In its 2013 Pre-Rulemaking Report, (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), the MAP supported the direction of the measure. Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of this proposed rule for a detailed discussion of data collection. We invite public comment on this proposal.

5. Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536)

This proposed measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery.

Cataract surgery is performed to improve a patient's vision and associated functioning. This outcome is achieved consistently through careful attention to the accurate measurement of axial length and corneal power and the appropriate selection of an IOL. Failure to achieve improved visual functioning after surgery in eyes without comorbid ocular conditions that could impact the success of the surgery would reflect care that should be assessed for opportunities for improvement. Evidence suggests that visual improvement occurs in about 86—98 percent of surgeries in eyes without comorbid conditions. However, with an annual volume of 2.8 million cataract surgeries in the United States, many of which are performed in hospital outpatient surgical departments, the impact could affect a significant number of patients per year.[9]

We are proposing to adopt this measure for the CY 2016 payment determination and subsequent years. The measure numerator is: Patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery, based on completing a pre-operative and post-operative visual function instrument. The measure denominator is: All patients aged 18 years and older in sample who had cataract surgery. There are no exclusions.

The specifications for this measure are available at *http://www.qualityforum.org/QPS/1536*. Additional information for the measure specifications can be found in the NQF Measure Evaluation available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=68317*.

In its 2013 Pre-Rulemaking Report, (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), the MAP supported the inclusion of the measure in the Hospital OQR Program and noted that the measure addresses a high impact condition not adequately addressed in the program measure set. The MAP added that this measure, which addresses outcomes, falls under a category of measures inadequately represented in the program measure set. Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of this proposed rule for a detailed discussion of data collection. We invite public comment on this proposal.

The proposed measure set for the Hospital OQR Program for the CY 2016 payment determination and subsequent years is listed in the table below.

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF#	Measure name
0287 ...	OP–1: Median Time to Fibrinolysis.
0288 ...	OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
0290 ...	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286 ...	OP–4: Aspirin at Arrival.
0289 ...	OP–5: Median Time to ECG.
0270 ...	OP–6: Timing of Antibiotic Prophylaxis.
0268 ...	OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
0514 ...	OP–8: MRI Lumbar Spine for Low Back Pain.
	OP–9: Mammography Follow-up Rates.
	OP–10: Abdomen CT—Use of Contrast Material.
0513 ...	OP–11: Thorax CT—Use of Contrast Material.
0489 ...	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669 ...	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*.
0491 ...	OP–17: Tracking Clinical Results between Visits.
0496 ...	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662 ...	OP–21: Median Time to Pain Management for Long Bone Fracture.

Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. Gastrointest Endosc 2006 Apr;63(4):546–57. *http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract*.

[9] National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at *http://www.qualitymeasures.ahrq.gov/content.aspx?id=27982*.

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF#	Measure name
	OP–22: ED- Patient Left Without Being Seen.
0661 ...	OP–23: ED- Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
	OP–25: Safe Surgery Checklist Use.
	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.**
0431 ...	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.***
0564 ...	OP–28: Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures.***
0658 ...	OP–29: Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients.***
0659 ...	OP–30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use***.
1536 ...	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.***

* Public reporting for OP–15 continues to be deferred at the time of this CY 2014 OPPS/ASC proposed rule.

** OP–26: Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v+6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs*.

*** New measures proposed for the CY 2016 payment determination and subsequent years.

F. Possible Hospital OQR Program Measure Topics for Future Consideration

The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, the use of HIT care coordination, patient safety, and volume. We anticipate that as EHR technology evolves and more infrastructure is put into place, we will have the capacity to accept electronic reporting of many clinical chart-abstracted measures that are currently part of the Hospital OQR Program using certified EHR technology. We are working diligently toward this goal. We believe that this progress, at a near future date, would significantly reduce the administrative burden on hospitals under the Hospital OQR Program to report chart-abstracted measures. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures targeted for e-specifications. This includes completing electronic specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications into certified EHR technology to capture and calculate the results, and implementing the systems.

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. Therefore, through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings, including partial hospitalization programs (PHPs) that are part of HOPDs.

We are considering the following measure domains for future measures: Clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency. We believe this approach will promote better care while bringing the Hospital OQR Program in line with other established quality reporting programs such as the Hospital IQR Program and the ASCQR Program.

We invite public comment on this approach and on our suggestions and rationale for possible measure topics for future consideration in the Hospital OQR Program.

In addition, we are soliciting comments on the following potential quality measure topics for PHPs in HOPDs: Poly-therapy with antipsychotic medications; Post-discharge of continuity of care; Alcohol screening; Alcohol and drug use; Tobacco use assessment; and Follow-up after hospitalization for mental illness. These topics would align measurement of PHPs in HOPDs with that of the IPFQR Program.

XIII. Hospital Outpatient Quality Reporting Program Updates

G. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2014 Payment Update

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, required by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent payment year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. All other hospitals paid under the OPPS that meet the reporting requirement receive the full OPPS payment update without the reduction. For a more detailed discussion of how the payment reduction for failure to meet the administrative, data collection, and data submission requirements of the Hospital OQR Program was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this proposed rule with comment period, which is available via the Internet on

the CMS Web site): ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' or ''U.'' We note that we are proposing to delete status indicator ''X'' as described in sections II.A.3. and XI. of this proposed rule. We also note that we are proposing to develop status indicator ''J1'' as part of the proposed comprehensive APC discussed in section II.A.2.e. of this proposed rule. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for applicable hospitals, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T''. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To implement the requirement to reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative weights by the reduced conversion factor. To determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for those hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply in those cases when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payments for hospitals that do not meet the Hospital OQR Program requirements. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when the criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. This policy conforms to current practice under the IPPS. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2014

We are proposing to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2014 annual payment update factor. For the CY 2014 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $71.273 by the proposed full conversion factor of $72.728. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2014 OPPS, we are proposing to apply the reporting ratio, when applicable, to all HCPCS codes to which we have assigned status indicators ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' and ''U'' (other than new technology APCs to which we have assigned status indicators ''S'' and ''T''). We note that we are proposing to delete status indicator ''X'' as described in sections II.A.3. and XI. of this proposed rule. We also note that we are proposing to develop status indicator ''J1'' as part of the proposed comprehensive APC discussed in section II.A.2.e. of this proposed rule and to apply the reporting ratio to the comprehensive APCs. We are proposing to continue to exclude services paid under New Technology APCs. We are proposing to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also are proposing to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we are proposing to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We invite public comment on these proposals.

H. Proposed Requirements for Reporting of Hospital OQR Data for the CY 2015 Payment Determination and Subsequent Years

1. Administrative Requirements for the CY 2015 Payment Determination and Subsequent Years

To participate successfully in the Hospital OQR Program, hospitals must meet administrative, data collection and submission, and data validation requirements (if applicable). Hospitals that do not meet Hospital OQR Program requirements, as well as hospitals not participating in the program and hospitals that withdraw from the program, will not receive the full OPPS

payment rate update. Instead, in accordance with section 1833(t)(17)(A) of the Act, those hospitals will receive a reduction of 2.0 percentage points to their OPD fee schedule increase factor for the applicable payment year.

We established administrative requirements for the payment determination requirements for the CY 2013 payment update and subsequent years in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479 through 74487). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68480 through 68481), we modified these requirements by extending the deadline for certain hospitals to submit a participation form. For the CY 2014 payment determination and subsequent years, we modified the deadline for hospitals that are not currently participating in the Hospital OQR Program and wish to participate, provided they have a Medicare acceptance date before January 1 of the year prior to the affected annual payment update. For example, 2013 would be the year prior to the affected CY 2014 annual payment update, and we are referring to an acceptance date before January 1, 2013. The hospitals must submit a participation form by July 31 rather than March 31 of the year prior to the affected annual payment update in order to participate in the Hospital OQR Program for purposes of the CY 2014 payment update. In the example, the deadline would be July 31, 2013.

The Hospital OQR Program procedural requirements are unchanged from those adopted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68480 through 68481). We are proposing to codify these procedural requirements at § 419.46(a). To participate in the Hospital OQR Program, a hospital—as defined in section 1886(d)(1)(B) of the Act and that is reimbursed under the OPPS—must:

- Register with QualityNet before beginning to report data.
- Identify and register a QualityNet security administrator as part of the registration process located on the QualityNet Web site (*http://www.QualityNet.org*);
- Complete and submit an online participation form available at the QualityNet Web site if this form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN). For Hospital OQR Program purposes, hospitals that share the same CCN are required to complete a single online participation form. Once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant until such time as it submits a withdrawal form to CMS or no longer has an effective Medicare provider agreement.

Deadlines to submit the notice of participation form are based on the date identified as a hospital's Medicare acceptance date:

- If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must complete and submit to CMS a completed Hospital OQR Notice of Participation Form by July 31 of the calendar year prior to the affected annual payment update.
- If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date.

Hospitals may withdraw from participating in the Hospital OQR Program and the procedural requirements for this are unchanged from those adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 77480). We are proposing to codify these procedural requirements at § 419.46(b). Under these procedures, a participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital may withdraw any time from January 1 to November 1 of the year prior to the affected annual payment update. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.43(h), and is required to submit a new participation form in order to participate in any future year of the Hospital OQR Program.

We invite public comment on this proposal.

2. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

a. Background

We refer readers to the following OPPS/ASC final rules with comment period for a history of measures adopted for the Hospital OQR Program, including lists of: 11 measures finalized for the CY 2011 payment determination (74 FR 60637); 15 measures finalized for the CY 2012 payment determination (75 FR 72083 through 72084); 23 measures finalized for the CY 2013 payment determination (75 FR 72090); 26 measures finalized for the CY 2014 and CY 2015 payment determination (76 FR 74469 and 74473) and no additional measures finalized for the CY 2015 payment determination (77 FR 68476 through 68478). In the CY 2013 OPPS/ASC final rule with comment period, we confirmed the removal of one measure for the CY 2013 payment determination and subsequent years (77 FR 68473 through 68474), confirmed the suspension of one measure for the CY 2014 payment determination (77 FR 68474 through 68476), and finalized the deferred data collection for one measure (77 FR 68476).

b. Effects of Proposed Changes on Data Submission for CY 2015 and CY 2016 Payment Determinations and Subsequent Years

For the CY 2015 payment determination and subsequent years, we are proposing to remove OP–19 as discussed in section XIII.C.2.a. of this proposed rule. Effective with January 1, 2013 encounters, we previously suspended OP–19 and have not used OP–19 data to meet requirements for any payment determination under the Hospital OQR Program or in public reporting. Therefore, our proposal to remove OP–19 from the Hospital OQR Program would not require a participating hospital to take any new action.

For the CY 2015 payment determination and subsequent years, we are proposing to remove OP–24 from the Hospital OQR program, as discussed in section XIII.C.2.b. of this proposed rule. To date, we have not required hospitals to submit data for OP–24. Based on this proposal, hospitals would not be required to take any new action; that is, they would continue having no requirement to abstract or submit data for OP–24.

For the CY 2016 payment determination and subsequent years, in section XIII.E. of this proposed rule we are proposing to add five additional measures to the program.

We would require hospitals to submit data for these measures annually via an online tool located on either the NHSN Web site or the QualityNet Web site depending on the measure. We discuss proposed data collection for each of these new measures by mode of data submission in the following sections of this proposed rule.

The proposed new measures are:

- OP–27: Influenza Vaccination Coverage among Healthcare Personnel;
- OP–28: Complications within 30 Days Following Cataract Surgery

Requiring Additional Surgical Procedures;

- OP–29: Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients;
- OP–30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and
- OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

c. General Requirements

The proposed Hospital OQR Program procedural requirements are unchanged from those discussed and adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74480 through 74482). We are proposing to codify the policy that, to be eligible to receive the full OPD fee schedule increase factor for any payment determination, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(17)(C) of the Act in a form and manner, and at a time specified by CMS. This means that hospitals must comply with our submission requirements for chart-abstracted data, population and sampling data, claims-based measure data, and Web-based quality measure data. We are proposing to codify these general submission requirements at § 419.46(c).

Submission deadlines by measure and data type are posted on the QualityNet Web site. In general, deadlines for patient-level data submitted directly to CMS would be approximately 4 months after the last day of each calendar quarter. For example, the submission deadline for data for services furnished during the first quarter of CY 2014 (January–March 2014) would be on or around August 1, 2014. We are proposing to codify language at § 419.46(c)(2) stating our practice of posting actual submission deadlines by measure and by data type on the QualityNet Web site (*http://www.QualityNet.org*).

We are proposing to codify our policies for initial data collection periods and submission deadlines for a hospital that did not participate in the previous year's Hospital OQR Program in § 419.46(c)(3) of our regulations. We refer readers to our previously finalized policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481) to establish data collection and submission requirements for the CY 2014 payment determination and subsequent years. To determine when a hospital that did not participate in a previous year's payment determination must begin collecting and submitting data to meet Hospital OQR Program requirements for a full annual payment update, we continue to use the January 1 Medicare acceptance date. If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must collect data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update, in addition to submitting a completed Hospital OQR Notice of Participation Form. If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must collect data for encounters beginning with the first full quarter following submission of the completed Hospital OQR Notice of Participation Form. Hospitals with a Medicare acceptance date before or after January 1 of the year prior to an affected annual payment update must follow data submission deadlines as specified on the QualityNet Web site.

We invite public comment on these proposals.

d. Proposed Chart-Abstracted Measure Requirements for the CY 2015 and CY 2016 Payment Determinations and Subsequent Years

The following chart-abstracted measures in the Hospital OQR Program require data submission for the CY 2015 payment determination and subsequent years:

- OP–1: Median Time to Fibrinolysis;
- OP–2: Fibrinolytic Therapy Received Within 30 Minutes;
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention;
- OP–4: Aspirin at Arrival;
- OP–5: Median Time to ECG;
- OP–6: Timing of Antibiotic Prophylaxis;
- OP–7: Prophylactic Antibiotic Selection for Surgical Patients;
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients;
- OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional;
- OP–21: ED—Median Time to Pain Management for Long Bone Fracture;
- OP–22: ED Patient Left Without Being Seen; and
- OP–23: ED—Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 Minutes of Arrival.

The form and manner for submission of one of these measures, OP–22: ED Patient Left Without Being Seen, is unique, and is detailed in section XV.G.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484). As discussed above, we are not proposing any new chart-abstracted measures where patient-level data is submitted directly to CMS in this proposed rule.

e. Proposed Claims-Based Measure Data Requirements for the CY 2015 Payment Determination and Subsequent Years

The table in section XIII.D. of this proposed rule includes measures that the Hospital OQR Program collects by accessing electronic Medicare claims data submitted by hospitals for reimbursement.

We are not proposing new claims-based measures in this proposed rule. Therefore, the following 6 claims-based measures will be included for the CY 2015 payment determination and subsequent years:

- OP–8: MRI Lumbar Spine for Low Back Pain;
- OP–9: Mammography Follow-Up Rates;
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–11: Thorax CT—Use of Contrast Material;
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery; and
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).

We deferred the public reporting of OP–15, a claims-based measure (76 FR 74456). We are not proposing any change to this policy. Public reporting for OP–15 continues to be deferred, and this deferral has no effect on any payment determinations at this time.

We will continue our policy of calculating the measures using the hospital's Medicare claims data as specified in the Hospital OQR Specifications Manual; therefore, no additional data submission is required for hospitals. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74483), we stated that for the CY 2014 payment update, we will use paid Medicare FFS claims for services furnished from January 1, 2011 to December 31, 2011.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68482 through 68485), for the CY 2015 payment determination, we finalized our proposal to use paid Medicare FFS claims for services from a 12 month period from July 1, 2012 through June 30, 2013 for the calculation of the claims-based measures. This is a departure from the traditional 12 month

calendar year period we have used for these measures. As stated in that final rule with comment period, we adopted this period in order to align the data period for inpatient and outpatient claims based measures reported on the *Hospital Compare* Web site, and also to be able to post more recent data for claims-based measures on the Web site. Under our policy prior to the CY 2013 final rule, the time period would have been January 1, 2011 to December 31, 2011, whereas, under the policy finalized in that final rule with comment period, the time period is July 1, 2012 to June 30, 2013.

For the CY 2016 payment determination and subsequent years, we are proposing to continue this approach and to use paid Medicare FFS claims for services from a 12 month period from July three years before the payment determination through June of the next year. For CY 2016, this 12 month period would be from July 1, 2013 through June 30, 2014 for the calculation of the claims-based measures. We invite public comment on this proposal.

f. Proposed Data Submission Requirements for Measure Data Submitted via Web-Based Tool for the CY 2016 Payment Determination and Subsequent Years

In previous rulemaking, we have referred to measures where data are submitted via a Web-based tool on a CMS Web site under our quality data reporting programs as structural measures (measures concerned with attributes of where care occurs, such as material resources, human resources, and organizational structure.[10] For example, the Hospital OQR Measure OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data is a structural measure. However, because measures where data is submitted in this manner may or may not be structural, for example, the Hospital IQR chart-abstracted, process of care measure PC–01: Elective Delivery Prior to 39 Completed Weeks Gestation, we have refined our terminology and now refer to the mode of data submission as Web-based.

Thus, the previously finalized Web-based measures where data is entered on a CMS Web site that we require for the CY 2015 payment determination and subsequent years are listed below:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data;
- OP–17: Tracking Clinical Results Between Visits;
- OP–22: ED Patient Left Without Being Seen;
- OP 25: Safe Surgery Check List Use; and
- OP 26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68483 through 68484), we finalized that, for the CY 2014 payment determination, hospitals are required to submit data on all Web-based measures between July 1, 2013 and November 1, 2013 with respect to the time period from January 1, 2012 to December 31, 2012. This schedule also applies to the encounter periods and deadlines to submit data for OP–22: ED Patient Left Without Being Seen. While patient-level data for this measure is collected via chart-abstraction, aggregate data is submitted using an online tool.

We also finalized in the CY 2013 OPPS/ASC final rule with comment period for the CY 2015 payment determination, that hospitals are required to submit data on all Web-based measure data between July 1, 2014 and November 1, 2014 with respect to the time period from January 1, 2013 to December 31, 2013.

We are proposing to apply a similar schedule for the CY 2016 payment determination and subsequent years. For the CY 2016 payment determination and subsequent years, we are proposing that hospitals would be required to submit data between July 1 and November 1 of the year prior to a payment determination with respect to the time period of January 1 to December 31 of two years prior to a payment determination year. Thus, for example, for the CY 2016 payment determination, hospitals would be required to submit data between July 1, 2015 and November 1, 2015 with respect to the time period of January 1, 2014 to December 31, 2014.

We are also proposing to apply the same mode of data collection and deadlines to the following proposed measures:

- OP–28: Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures;
- OP–29: Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients;
- OP–30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and
- OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

Specifically, for data collection, we are proposing that hospitals submit aggregate-level data through the CMS Web-based tool (the QualityNet Web site). As with OP–22, hospitals would submit all the data required for a particular program year once annually during the data submission window we are proposing above, and would do so via the Outpatient section on the QualityNet secure Web site. While we are proposing submission deadlines with an annual frequency, the data input forms on the QualityNet Web site for such submission will require hospitals to submit aggregate data represented by each separate quarter. We are proposing to both use the Web-based collection tool and collect aggregate-level data because we believe these options are less burdensome to hospitals than patient-level reporting.

While this proposal applies to the CY 2016 payment determination and subsequent years, we summarize below, for chart-abstracted measures collected via the Web-based tool, the proposed and finalized measures, data collection periods, and deadlines for just the CY 2016 payment determination.

[10] Maintz, J. Defining and Classifying Clinical Indicators for Quality Improvement, Inter J Quality Health Care (2003) 15(6), 523–530).

PROPOSED AND FINALIZED CHART-ABSTRACTED MEASURES WITH DATA COLLECTION BY WEB-BASED TOOL: CY 2016 PAYMENT DETERMINATION

Measure	Hospital OQR program status	Encounter dates	Data submission timeframe
OP–22: ED Patient Left Without Being Seen	Finalized	January 1, 2014–December 31, 2014.	July 1, 2015–November 1, 2015.
OP–28: Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures.	Proposed	January 1, 2014–December 31, 2014.	July 1, 2015–November 1, 2015.
OP–29: Endoscopy/poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients.	Proposed	January 1, 2014–December 31, 2014.	July 1, 2015–November 1, 2015.
OP–30: Endoscopy/poly surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.	Proposed	January 1, 2014–December 31, 2014.	July 1, 2015–November 1, 2015.
OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.	Proposed	January 1, 2014–December 31, 2014.	July 1, 2015–November 1, 2015.

We recognize that aggregate-level reporting has the potential to result in less accurate measure rates than patient-level reporting. However, to reduce burden for hospitals, we believe that an aggregate data submission approach is the preferable approach at this time.

We invite public comment on these proposals.

g. Proposed Data Submission Requirements for a Measure Reported via NHSN for the CY 2016 Payment Determination and Subsequent Years

As discussed above, we are proposing to add the measure OP–27: Influenza Vaccination Coverage among Healthcare Personnel to the Hospital OQR Program measure set. We are also proposing to use the data submission and reporting standard procedures set forth by CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting procedures. We believe that these procedures are feasible because they are already widely used by over 4,000 hospitals reporting HAI data using NHSN. Our proposal seeks to reduce hospital burden by aligning our data submission and reporting procedures with NHSN procedures currently used by hospitals who participate in the reporting requirements for the Hospital IQR Program as well as hospitals in the 30 States and the District of Columbia that mandate HAI reporting via NHSN.

We are proposing to adopt the NHSN HAI measure data collection timeframe of October 1 through March 31st, as previously finalized in the Hospital IQR Program (76 FR 51631 through 51633), which links data collection to the time period in which influenza vaccinations are administered during the influenza season. Because data for this measure would be collected seasonally, we are proposing that hospitals submit their data for this measure to NHSN for purposes of the Hospital OQR Program by May 15th of the calendar year in which the vaccination season has ended. For example, for vaccinations given from October 1, 2014 (or when the vaccine becomes available) to March 31, 2015, the submission deadline would be May 15, 2015. This data submission deadline for this measure corresponds to that proposed by the Hospital IQR Program (78 FR 27700).

We invite public comment on these proposals.

h. Population and Sampling Data Requirements for the CY 2015 Payment Determination and Subsequent Years

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484), for the CY 2014 payment determination and subsequent years, we continued our policy that hospitals may submit voluntarily on a quarterly basis, aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted, but they will not be required to do so. Where hospitals do choose to submit this data, the deadlines for submission are the same as those for reporting data for chart-abstracted measures, and hospitals may also choose to submit data prior to these deadlines. The deadline schedule is available on the QualityNet Web site. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72101 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of these policies.

We are not proposing any changes to this policy.

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2015 Payment Determination and Subsequent Years

a. Selection of Hospitals for Data Validation of Chart-Abstracted Measures for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2012 and CY 2013 OPPS/ASC final rules with comment period (76 FR 74484 through 74487 and 77 FR 68484 through 68487) for a discussion of finalized policies regarding our sampling methodology, including sample size, eligibility for validation selection, and encounter minimums for patient-level data for measures where data is obtained from chart abstraction and submitted directly to CMS from selected hospitals. We are not proposing any changes to these policies.

We are, however, proposing to codify at § 419.46(e) of our regulations the existing policy that we may validate one or more measures selected under section 1833(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals. Upon written request, a hospital must submit to CMS or its contractor supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request. A hospital meets the validation requirement with respect to a fiscal year if it achieves at least a 75-percent reliability score, as determined by CMS.

We invite public comment on our proposal to codify these requirements.

b. Targeting Criteria for Data Validation Selection for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68485 through 68486) for a discussion of our targeting criteria. We are not proposing any changes to this policy.

c. Methodology for Encounter Selection for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486) for a discussion of our methodology for encounter selection. We are not proposing any changes to this policy.

d. Medical Record Documentation Requests for Validation and Validation Score Calculation for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487) for a discussion of our procedures for requesting medical record documentation for validation and validation score calculation. We are not proposing any changes to our procedures regarding medical record requests.

However, we are proposing to codify these procedures at § 419.46(e)(1) and (e)(2) as summarized below:

- CMS may validate one or more measures selected under section 1833(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals.
- Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request.
- A hospital meets the validation requirement with respect to a fiscal year if it achieves at least a 75-percent reliability score, as determined by CMS.

We invite public comment on our proposal to codify these procedures.

I. Proposed Hospital OQR Reconsideration and Appeals Procedures for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487) for a discussion of our reconsideration and appeals procedures. We are proposing one change to the reconsideration request procedures to ensure our deadline for reconsideration requests will always fall on a business day. We also are proposing to codify the process, including our proposal to change the deadline by which participating hospitals may submit requests for reconsideration at § 419.46(f) of our regulations.

Under the proposed change to our procedures, a hospital seeking reconsideration would submit to CMS, via the QualityNet Web site, a Reconsideration Request form that will be made available on the QualityNet Web site. Where we have required that this form must be submitted by February 3 of the affected payment year (for example, for the CY 2014 payment determination, the request was required to be submitted by February 3, 2014), we are proposing to modify this requirement so that the Reconsideration Request form would be required to be submitted on the first business day in February of the affected payment year. If this proposal is finalized, the Reconsideration Request form for the CY 2014 payment determination would be required on February 3, 2014, which is a Monday, and the form for the CY 2015 payment determination would be required on February 2, 2015, which is also a Monday. We note that while we use the CY 2014 and 2015 payment determinations as examples, we are proposing this policy for the CY 2014 payment determination and subsequent years. The other requirements of the form would remain unchanged. We request public comment on this proposal.

We also are proposing to codify this process by which participating hospitals may submit requests for reconsideration including our proposal to change the reconsideration request deadline at § 419.46(f). Under these proposed procedures, the hospital must submit to CMS via QualityNet, a reconsideration request via the QualityNet Web site, no later than the first business day of the month of February of the affected year containing the following information:

- The hospital's CMS Certification Number (CCN);
- The name of the hospital;
- The CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital;
- The hospital's basis for requesting reconsideration. The hospital must identify its specific reason(s) for believing it should not be subject to the reduced annual payment update;
- The hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).
- The hospital-designated personnel's signature;
- A copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and
- If the hospital is requesting reconsideration on the basis that CMS has determined it did not meet an affected payment determination year's validation requirement set forth in paragraph (e)(1) of this section, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered.

We also are proposing to codify language at § 419.46(f)(3) stating that a hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board.

While we are not proposing to codify the following process, we note that, after receiving a request for reconsideration, CMS—

- Provides an email acknowledgement, using the contact information provided in the reconsideration request, to the designated hospital personnel notifying them that the hospital's request has been received.
- Provides a formal response to the hospital-designated personnel, using the contact information provided in the reconsideration request, notifying the hospital of the outcome of the reconsideration process.
- Applies policies regarding the scope of our review when a hospital requests reconsideration because it failed our validation requirement.

These policies are as follows:

- If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more data elements were classified as mismatches, we only consider the

hospital's request if the hospital timely submitted all requested medical record documentation to the CMS contractor each quarter under the validation process.

- If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more of the complete medical records it submitted during the quarterly validation process was classified as an invalid record selection (that is, the CMS contractor determined that one or more of the complete medical records submitted by the hospital did not match what was requested), thus resulting in a zero validation score for the encounter(s), our review is initially limited. We will review only to determine whether the medical documentation submitted in response to the designated CMS contractor's request was the correct and complete documentation. If we determine that the hospital did submit correct and complete medical documentation, we abstract the data elements and compute a new validation score for the encounter. If we conclude that the hospital did not submit correct and complete medical record documentation, we do not further consider the hospital's request.

- If a hospital requests reconsideration on the basis that it disagrees with a determination that it did not submit the requested medical record documentation to the CMS contractor within the proposed 30 calendar day timeframe, our review is initially limited to determining whether the CMS contractor received the requested medical record documentation within 30 calendar days, and whether the hospital received the initial medical record request and reminder notice. If we determine that the CMS contractor timely received copies of the requested medical record documentation, we abstract data elements from the medical record documentation submitted by the hospital and compute a validation score for the hospital. If we determine that the hospital received two letters requesting medical documentation but did not submit the requested documentation within the 30 calendar day period, we do not further consider the hospital's request.

If a hospital is dissatisfied with the result of a Hospital OQR reconsideration decision, the hospital is able to file an appeal under 42 CFR Part 405, Subpart R (PRRB appeal).

We invite public comment on these proposals.

J. Extraordinary Circumstances Extension or Waiver for the CY 2014 Payment Determination and Subsequent Years

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal to not penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489) for a complete discussion of our extraordinary circumstances extension or waiver process under the Hospital OQR Program.

We are proposing one change to our process for hospitals to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital. Specifically, we are proposing that we may grant a waiver or extension to hospitals if we determine that a systemic problem with one of our data collection systems directly or indirectly affected the ability of hospitals to submit data. Because we do not anticipate that such systemic errors will happen often, we do not anticipate granting a waiver or extension on this basis frequently.

We also are proposing to codify language for the general requirements for our extension or waiver process including the proposal for systemic errors at § 419.46(d) as described below:

CMS may grant an extension or waiver of one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an extension or waiver as follows:

- Upon request by the hospital. Specific requirements for submission of a request for an extension or waiver are available on the QualityNet Web site.

- At the discretion of CMS. CMS may grant waivers or extensions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

For the hospital to request consideration for an extension or waiver of the requirement to submit quality data or medical record documentation for one or more quarters, a hospital would follow specific requirements for submission of a request available on QualityNet. While we are not proposing to codify the following process, we note that, the following information must appear on the request form:

- Hospital CCN;

- Hospital Name;

- CEO or other hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);

- Hospital's reason for requesting an extension or waiver;

- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and

- A date when the hospital believes it would again be able to submit Hospital OQR data and/or medical record documentation, and a justification for the proposed date.

The request form must be signed by the hospital's designated contact, whether or not that individual is the CEO. A request form is required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, CMS would—

(1) Provide an email acknowledgement using the contact information provided in the request notifying the designated contact that the hospital's request has been received;

(2) Provide a formal response to the hospital's designated contact using the contact information provided in the request notifying them of our decision; and

(3) Complete our review and communicate our response within 90 days following our receipt of such a request.

We can also grant waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as when an act of nature (for example, hurricane) affects an entire region or locale or a systemic problem with one of our data collection systems directly or indirectly affects data submission. If we make the determination to grant a waiver or extension to hospitals in a region or locale, we would communicate this decision to hospitals and vendors through routine communication channels, including but not limited to emails and notices on the QualityNet Web site.

We invite public comment on these proposals.

XIV. Hospital Value-Based Purchasing (VBP) Program Updates

A. Background

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital Value-Based Purchasing (VBP) Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

B. Proposal for Additional CMS Appeals Review Process

1. Statutory Basis

Section 1886(o)(11)(A) of the Act requires the Secretary to establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards (section 1886(o)(3)(A) of the Act) and the hospital performance score (section 1886(o)(5) of the Act).

Under section 1886(o)(11)(B) of the Act, there is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following: (1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount; (2) the determination of the amount of funding available for the value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act; (3) the establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act; (4) the measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act; (5) the methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores; or (6) the validation methodology specified in section 1886(b)(3)(B)(XI) of the Act.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53581), we finalized an administrative appeals process and codified that process at 42 CFR 412.167.

2. Independent CMS Review Proposal

In this proposed rule, for the Hospital VBP Program, we are proposing to implement an independent CMS review that will be an additional appeal process available to the hospitals, beyond the existing review and corrections process (77 FR 53578 through 53581 and 76 FR 74544 through 74547) and appeal process codified at 42 CFR 412.167. We are proposing that a hospital would be able to request this additional independent CMS review only if it first completes the appeal process at 42 CFR 412.167(b) and is dissatisfied with the result. We believe that our proposal to require hospitals to complete the existing appeal process at 42 CFR 412.167(b) before they can request an additional independent CMS review will facilitate the efficient resolution of many disputed issues, thus decreasing the number of independent CMS reviews that are requested. We intend to provide hospitals with our independent review decision within 90 calendar days following the receipt of a hospital's independent review request. We also are proposing to codify this policy in our regulations at 42 CFR 412.167 by redesignating the existing paragraph (c) as paragraph (d), and inserting a new paragraph (c). We are inviting public comments on these proposals.

C. Proposed Performance and Baseline Periods for Certain Outcome Measures for the FY 2016 Hospital VBP Program

As described in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27610 through 27611), we have proposed to adopt CLABSI, CAUTI, and SSI, which are measures reported to CDC's National Healthcare Safety Network (NHSN), for the FY 2016 Hospital VBP Program. However, when we published that proposed rule, we inadvertently did not make FY 2016 performance and baseline period proposals for these proposed measures. We are proposing to adopt FY 2016 performance and baseline periods for these measures in this proposed rule so that we have enough time to consider and respond to public comments before the proposed start of the performance periods.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53597 through 53598), we finalized an 11-month performance period for the CLABSI measure for the FY 2015 Hospital VBP Program (February 1, 2013 through December 31, 2013), with a corresponding baseline period of January 1, 2011 through December 31, 2011. While we adopted an 11-month performance period for the CLABSI measure for FY 2015 based on its posting date on the *Hospital Compare* Web site, beginning with FY 2016, we are proposing to align the NHSN measures' performance and baseline periods with other domains' performance and baseline periods, where possible, and with the calendar year. As we have stated with regard to other domains, a 12-month performance period provides us more data on which to score hospital performance, which is an important goal both for CMS and for stakeholders.

Therefore, we are proposing to adopt CY 2014 (January 1, 2014 through December 31, 2014) as the performance period for the CLABSI, CAUTI, and SSI measures for the FY 2016 Hospital VBP Program, with CY 2012 (January 1, 2012 through December 31, 2012) as the baseline period. We are inviting public comments on these proposals.

The proposed performance and baseline periods for the CAUTI, CLABSI, and SSI measures for the FY 2016 Hospital VBP Program appear in the following table.

PROPOSED PERFORMANCE AND BASELINE PERIODS FOR CAUTI/CLABSI/SSI UNDER THE FY 2016 HOSPITAL VBP PROGRA

Domain	Baseline period	Performance period
Outcome • CAUTI/CLABSI/SSI ...	• January 1, 2012–December 31, 2012	• January 1, 2014–December 31, 2014.

XV. Proposed Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of this proposed rule for a general overview of our quality reporting programs.

2. Statutory History of the ASC Quality Reporting (ASCQR) Program

We refer readers to section XIV.K.1. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68780), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60656), and the CY 2011 OPPS/ASC final rule with comment period (75 FR 72109), we did not implement a quality data reporting program for ASCs. We determined that it would be more appropriate to allow ASCs to acquire some experience with the revised ASC payment system, which was implemented for CY 2008, before implementing new quality reporting requirements.

However, in these rules, we indicated that we intended to implement a quality reporting program for ASCs in the future. In preparation for proposing a quality reporting program for ASCs, in the CY 2011 OPPS/ASC proposed rule (75 FR 46383), we solicited public comment on 10 measures.

In addition to CMS preparing to propose implementation of a quality reporting program for ASCs, HHS developed a plan to implement a value-based purchasing (VBP) program for payments under title XVIII of the Act for ASCs, and submitted a report to Congress entitled ''Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan'' that details this plan. The plan and the report to Congress were required under section 3006(f) of the Affordable Care Act as added by section 10301(a) of the Affordable Care Act. The report is found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/Downloads/C_ASC_RTC–2011.pdf*. Currently, we do not have express statutory authority to implement an ASC VBP program.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination. We adopted quality measures for the CY 2014, CY 2015, and CY 2016 payment determinations and subsequent years, and finalized some data collection and reporting timeframes for these measures. We also adopted policies with respect to the maintenance of technical specifications and the updating of measures, publication of ASCQR Program data, and, for the CY 2014 payment determination, data collection and submission requirements for the claims-based measures. For a discussion of these final policies, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517).

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74515), we indicated our intent to issue proposals for administrative requirements, data validation and completeness requirements, and reconsideration and appeals processes in the FY 2013 IPPS/LTCH PPS proposed rule, rather than in the CY 2013 OPPS/ASC proposed rule, because the FY 2013 IPPS/LTCH PPS proposed rule was scheduled to be finalized earlier and prior to data collection for the CY 2014 payment determination, which was to begin with services furnished on October 1, 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 through 53644), we issued final policies for administrative requirements, data completeness requirements, extraordinary circumstances waiver or extension requests, and a reconsideration process. For a complete discussion of these policies, we refer readers to the FY 2013 IPPS/LTCH PPS final rule.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68492 through 68500), we issued final policies regarding our approach to selecting quality measures, reporting requirements, and payment reductions for ASCs that fail to meet the ASCQR Program requirements.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the considerations we use for the selection of ASCQR Program quality measures.

2. ASCQR Program Quality Measures Adopted in Previous Rulemaking

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination and adopted measures for the CY 2014, CY 2015, and CY 2016 payment determinations. In an effort to streamline the rulemaking process, we also finalized our policy that, when we adopt measures for the ASCQR Program, these measures are automatically adopted for all subsequent years payment determinations unless we propose to remove, suspend, or replace the measures (76 FR 74494, 74504, 74509, and 74510).

The quality measures that we have previously adopted are listed below.

ASC Program Measurement Set Adopted in Previous Rulemaking

ASC–1: Patient Burn.*
ASC–2: Patient Fall.*
ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.*
ASC–4: Hospital Transfer/Admission.*
ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing.*
ASC–6: Safe Surgery Checklist Use.**
ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures.**
Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754*
ASC–8: Influenza Vaccination Coverage among Healthcare Personnel***

*New measure for the CY 2014 payment determination.
**New measure for the CY 2015 payment determination.
***New measure for the CY 2016 payment determination.

3. Proposed Additional ASCQR Program Quality Measures for the CY 2016 Payment Determination and Subsequent Years

We are proposing quality measures for the CY 2016 payment determination and subsequent years based on our approach for future measure selection and development finalized in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494), which includes, among other considerations, aligning the ASCQR Program measures with our efforts in other clinical care settings and taking into account the views of the MAP.

We believe that ASCs and HOPDs are similar in their delivery of surgical and related nonsurgical services. Therefore, we seek to propose quality measures that can be applied to both HOPDs and ASCs to the extent possible because many of the same surgical procedures are performed in both of these settings. Measure harmonization assures that quality of care for similar services is measured in a comparable manner across settings. This approach would provide meaningful information for Medicare beneficiaries to make informed decisions.

Section 3014 of the Affordable Care Act added section 1890A of the Act establishing a pre-rulemaking process, which, among other steps, requires the Secretary to take into consideration the input from multi-stakeholder groups in selecting certain categories of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. As part of the pre-rulemaking process, the consensus-based entity that CMS must contract with under section 1890 of the Act (currently NQF), convened the multi-stakeholder groups, referred to as the MAP. The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of the categories of measures in section 1890(b)(7)(B), which includes measures for use in certain specific Medicare programs, measures for use in reporting performance information to the public, and measures for use in health care programs other than for use under the Act.

After we selected quality measures that we might propose for the ASCQR Program based on our established policies regarding the approach to selecting quality measures in CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494), we included the measures in a publicly available document entitled ''List of Measures Under Consideration for December 1, 2012'' in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP in its ''MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS,'' which has been made available on the NQF Web site at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.* We considered the input and recommendations provided by the MAP in selecting measures to propose for the ASCQR Program.

In addition, in its 2013 Pre-Rulemaking Report, the MAP also supports: (1) HHS' efforts to move toward greater alignment across the Hospital OQR and ASCQR Programs; and (2) the inclusion of ASCs within a broader approach to measuring performance and improving care that is aligned across health care settings (page 35, MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS).

For the CY 2016 payment determination and subsequent years, we are proposing to adopt four measures for the ASCQR Program, all of which were reviewed by the MAP and three of which are NQF-endorsed for the ASC setting: (a) Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures; (b) Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients (NQF #0658); (c) Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); and (d) Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

For purposes of the ASCQR Program, sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment. The proposed measures are described in greater detail below.

We are proposing that data collection for these four measures would begin in CY 2014. We refer readers to section XV.D. of this proposed rule for detailed discussion of data collection and submission time frames. We are proposing to collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these four proposed chart-abstracted measures via an online Web-based tool that would be made available to ASCs via the QualityNet Web site. This online Web-based tool is currently in use in the ASCQR Program to collect measure information for ASC–6 (Safe Surgery Checklist Use) and ASC–7 (ASC Facility Volume Data on Selected ASC Surgical Procedures). We invite public comment on these proposals. More information regarding this proposed method of collection is provided in section XV.D.5.c. of this proposed rule.

To advance our efforts to collect high quality data on all ASC patients for the ASCQR measures while minimizing burden for ASCs, we also seek public comment on alternative data collection strategies for these four proposed measures. In particular, we seek comment on collection of patient-level data through registries or other third party data aggregators, and via certified EHR technology, along with the potential timing for doing so.

a. Complications Within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures

It is uncommon to have complications that may result in a permanent loss of vision following cataract surgery. Cataract surgery has become safer and more effective due to advances in technology and surgical skills over the last 30 years. Based on an analysis of Managed Care Organization data, it is estimated that the annual volume for cataract surgeries is 2.8 million in the U.S. with the rate of cataract surgery complications being 1 to 2 percent. However, with an annual volume of 2.8 million cataract surgeries in the United States, a 2 percent rate is significant and translates to over 36,000 surgeries associated with complications.[11]

Thus, for the CY 2016 payment determination and subsequent years, we are proposing to adopt the Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures

[11] National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at *http://qualitymeasures.ahrq.gov/content.aspx?id=27981&search=complications+within+30+days+following+cataract+surgery.*

measure, which assesses the ''[p]ercentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL retinal detachment, or wound dehiscence.'' This outcome measure seeks to identify those complications from surgery that can reasonably be attributed to the surgery. It focuses on patient safety and monitoring for events that, while uncommon, can signify important issues in the care being provided. The numerator for this measure is the number of ''[p]atients who had one or more specified operative procedures for any of the following major complications within 30 days following cataract surgery: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.'' The denominator for this measure is the total number of ''[p]atients aged 18 years and older who had cataract surgery and no significant pre-operative ocular conditions impacting the surgical complication rate.'' This measure excludes ''[p]atients with certain comorbid conditions impacting the surgical complication rate.'' The measure specifications can be found at: *http://www.qualityforum.org/QPS/0564.* This measure has been endorsed by NQF for the ''Ambulatory Care: Clinic'' setting (NQF #0564) but, currently, is not NQF-endorsed for the ASC setting.

We believe this measure meets the statutory requirements discussed above. This measure is not NQF-endorsed in the ASC setting and we could not find any other comparable measure that is specifically endorsed for the ASC setting. However, we believe that this measure is appropriate for the measurement of quality of care furnished by ASCs because this procedure is commonly performed in ASCs and, as discussed above, can signify important issues in the care being provided in ASCs. Further, this measure reflects consensus among affected parties as it has been endorsed by NQF for the ''Ambulatory Care: Clinic'' setting. We believe that this consensus also applies to the same surgeries that are performed in other ambulatory settings, such as ASCs and HOPDs. Given the high volume of cataract surgeries performed in ambulatory care settings and the potential 2 percent complication rate, we believe it is important for us to include this measure in the ASCQR Program measure set, and that this is an appropriate application of NQF #0564 to the ASC setting.

We note that section 1833(t)(17) of the Act does not require that each measure we adopt be endorsed by a national consensus building entity. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act applies to the ASCQR program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. In its 2013 Pre-Rulemaking Report, the MAP supported inclusion of this measure in the ASCQR Program and noted that this measure ''[a]ddresses a high impact condition not adequately addressed in the program measure set.'' Currently, the NQF endorsement for this measure is time-limited.

We invite public comment on this proposal.

b. Endoscopy/Poly Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)

The American Cancer Society's current guidelines recommend colonoscopy screening at 10-year intervals [12] for the average risk population (*http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-acs-recommendations*).

For the CY 2016 payment and subsequent years, we are proposing to adopt the Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients measure, which assesses the ''[p]ercentage of patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.'' Performing colonoscopy too frequently increases a patients' exposure to procedural harm. This measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years. This measure is NQF-endorsed for the ASC setting. The numerator for this measure is the number of ''[p]atients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.'' The denominator for this measure is the total number of ''[p]atients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy.'' The measure excludes patients whose medical records contain reason(s) for recommending a follow up interval of less than 10 years. The specifications for this measure can be found at: *http://www.qualityforum.org/QPS/0658.*

We believe this measure meets the statutory requirements discussed above. This measure is appropriate for the measurement of quality of care furnished by ASCs because colonoscopy screening is commonly performed in ASCs and this measure was developed to specifically measure quality of care furnished by ASCs. We also believe it meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is NQF-endorsed for the ASC setting.

In its 2013 Pre-Rulemaking Report, the MAP supported the direction of this measure. Currently, the NQF endorsement for this measure is time-limited.

We invite public comment on this proposal.

c. Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients With a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659)

According to the American Cancer Society, in patients with increased or high risk of colorectal cancer, colonoscopy screening is recommended based on risk factors. One such factor is a history of adenomatous polyps. The frequency of colonoscopy screening varies depending on the size and amount of polyps found; however, the general recommendation is a 3 year follow-up (*http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-acs-recommendations*). A randomized trial of 699 patients showed that after newly diagnosed adenomatous polyps have been removed by colonoscopy, follow-up colonoscopy at 3 years detects important colonic

[12] Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. Gastrointest Endosc 2006 Apr;63(4):546–57. *http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract.*

lesions as effectively as follow-up colonoscopy at both 1 and 3 years.[13]

For the CY 2016 payment determination and subsequent years, we are proposing to adopt the Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use measure, which assesses the ''[p]ercentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report'' This measure is NQF-endorsed for the ASC setting. The numerator for this measure is the number of ''[p]atients who had an interval of 3 or more years since their last colonoscopy.'' The denominator for this measure is the total number of ''[p]atients aged 18 years and older receiving a surveillance colonoscopy with a history of a prior colonic polyp in a previous colonoscopy.'' This measure excludes patients with: (1) Documentation of medical reason(s) for an interval of less than 3 years since the last colonoscopy (for example, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas); or (2) documentation of a system reason(s) for an interval of less than 3 years since the last colonoscopy (for example, unable to locate previous colonoscopy report, previous colonoscopy report was incomplete). The specifications for this measure can be found at: *http://www.qualityforum.org/QPS/0659*.

We believe this measure meets the statutory requirements discussed above. This measure is appropriate for the measurement of quality of care furnished by ASCs because colonoscopy is commonly performed in ASCs and this measure was developed to specifically measure quality of care furnished by ASCs. We also believe it meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is NQF-endorsed for the ASC setting.

In its 2013 Pre-Rulemaking Report, the MAP supported the direction of this measure. Currently, the NQF endorsement for this measure is time-limited.

We invite public comment on this proposal.

d. Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536)

Cataract surgery is performed to improve a patient's vision and associated functioning. This outcome is achieved consistently with careful attention to the accurate measurement of axial length and corneal power and the appropriate selection of an IOL lens. Failure to achieve improved visual functioning after surgery in eyes without comorbid ocular conditions that could impact the success of the surgery would reflect care that should be assessed for opportunities for improvement. Evidence suggests that visual improvement occurs in about 86 to 98 percent of surgeries in eyes without comorbid conditions. However, with an annual volume of 2.8 million cataract surgeries in the U.S., an improvement rate from 86 to 98 percent could impact a significant number of patients per year.[14]

For the CY 2016 payment determination and subsequent years, we are proposing to adopt the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure, which assesses the ''[p]ercentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery.'' This measure is NQF-endorsed for the ASC setting. The measure numerator is the number of ''[p]atients 18 years and older in sample who had improvement in visual function achieved within 90 days following cataract surgery, based on completing a pre-operative and post-operative visual function instrument.'' The measure denominator is the total number of ''[p]atients aged 18 years and older in sample who had cataract surgery.'' There are no exclusions. The specifications for this measure are available at: *http://www.qualityforum.org/QPS/1536.* Additional information for the measure specifications can be found in the NQF Measure Evaluation available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=68317.*

We believe this measure meets the statutory requirements discussed above. This measure is appropriate for the measurement of quality of care furnished by ASCs because cataract surgery is commonly performed in ASCs and this measure was developed to specifically measure quality of care furnished by ASCs.'' We believe it also meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is NQF-endorsed for the ASC setting.

In its 2013 Pre-Rulemaking Report, the MAP supported the inclusion of this measure in the ASCQR Program and noted that this measure ''[a]ddresses a high-impact condition not adequately addressed in the program measure set.''

We invite public comment on this proposal.

In summary, we are proposing to adopt four new measures for the ASCQR Program for the CY 2016 payment determination and subsequent years, with data collection beginning in CY 2014, as discussed in section XV.D.7.of this proposed rule. We are proposing to collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these four proposed chart-abstracted measures via an online Web-based tool that will be made available to ASCs via the QualityNet Web site. The proposed new measures for the CY 2016 payment determination and subsequent years for the ASCQR Program are listed in the table below.

PROPOSED NEW ASC PROGRAM MEASURE SET FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
0564*	Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures.
0658	Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients.
0659	Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.

[13] Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. Gastrointest Endosc 2006 Apr;63(4):546–57. *http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract.*

[14] National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at *http://www.qualitymeasures.ahrq.gov/content.aspx?id=27982.*

PROPOSED NEW ASC PROGRAM MEASURE SET FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF No.	Measure name
1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

*This measure has not been NQF endorsed for the ASC setting.

4. ASCQR Program Measure Topics for Future Consideration

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the ASC setting. Through future rulemaking, we intend to propose new measures that address clinical quality of care, patient safety, care coordination, patient experience of care, surgical outcomes, surgical complications, complications of anesthesia, and patient reported outcomes of care. We invite public comment on these measurement topics.

5. Technical Specification Updates and Data Publication

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures (76 FR 74513 through 74514). In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established an additional subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. We believe that a measure can be updated through this subregulatory process provided it is a nonsubstantive change. We expect to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis.

Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that non-substantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. We will revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. As stated in CY 2009 OPPS/ASC final rule with comment period, we also will post the updates on the QualityNet Web site at: *https://www.QualityNet.org.* We will provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary. We generally release the Hospital OQR Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for nonsubstantive changes such as changes to ICD–9, CPT, NUBC, and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the Hospital OQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice.

We believe that the policy finalized in the CY 2009 OPPS/ASC final rule with comment period adequately balances our need to incorporate non-substantive NQF updates to NQF-endorsed Hospital OQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF endorsement process incorporates an opportunity for public comment and engagement in the measure maintenance process. These policies regarding what is considered substantive versus non-substantive apply to all measures in the Hospital OQR Program.

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures (76 FR 74513 through 74514) and, in the CY 2013 OPPS/ASC final rule with comment period, we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR program policy. We refer readers to the CY 2013 OPPS/ASC final rule with comment period for a discussion of the process for updating the ASCQR Program quality measures (77 FR 68496 through 68497).

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we also finalized a policy to make data that an ASC submitted for the ASCQR program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. These data will be displayed at the CCN level.

We are not proposing any changes to these policies.

C. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

Section 1833(i)(2)(D)(iv) of the Act states that the Secretary may implement the revised ASC payment system ''in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).'' Paragraph (7) contains subparagraphs (A) and (B). Subparagraph (A) of paragraph (7) states the Secretary may provide that an ASC that does not submit ''data required to be submitted on measures selected under this paragraph with respect to a year'' to the Secretary in accordance with this paragraph will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. It also specifies that this reduction applies only with respect to the year involved and will not be taken into account in computing any annual increase factor for a subsequent year. Subparagraph (B) of paragraph (7) makes many of the provisions of the Hospital OQR Program applicable to the ASCQR Program ''[e]xcept as the Secretary may otherwise provide.'' Finally, section 1833(i)(2)(D)(v) of the Act states that, in implementing the revised ASC payment

system for 2011 and each subsequent year, ''any annual update under such system for the year, after application of clause (iv) [regarding the reduction in the annual update for failure to report on quality measures] shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).'' Section 1833(i)(2)(D)(v) of the Act also states that the ''application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the [revised ASC payment system] for a year being less than such payment rates for the preceding year.''

2. Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for the CY 2015 Payment Determination and Subsequent Years

The national unadjusted payment rates for many services paid under the ASC payment system equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. Currently, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the MFP-adjusted CPI–U update factor, which is the adjustment set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted CPI–U update factor is the Consumer Price Index for all urban consumers (CPI–U), which currently is the annual update for the ASC payment system, minus the MFP adjustment. As discussed in the CY 2011 MPFS final rule with comment period (75 FR 73397), if the CPI–U is a negative number, the CPI–U would be held to zero. Under the ASCQR Program, any annual update would be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction would apply beginning with the CY 2014 payment rates. For a complete discussion of the calculation of the ASC conversion factor, we refer readers to section XII.G. of this proposed rule.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this proposed rule, which are available via the Internet on the CMS Web site): ''A2,'' ''G2,'' ''P2,'' ''R2,'' ''Z2,'' as well as the service portion of device- intensive procedures identified by ''J8.'' We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor.

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2,'' ''G2,'' ''J8,'' ''P2,'' ''R2,'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures and radiology services where payment is based on the MPFS PE RVU amount and a few other specific services that receive cost-based payment. As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update.

Office-based surgical procedures (performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.C.1.b. of this proposed rule) are paid at the lesser of the MPFS non-facility PE RVU-based amounts and the standard ASC ratesetting methodology. We finalized our proposal that the standard ASC ratesetting methodology for this comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to an office-based or radiology procedure is consistent for each HCPCS code regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced copayment liability for beneficiaries. Therefore, we finalized our proposal in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500) that the Medicare beneficiary's national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would be based on the reduced national unadjusted payment rate.

We finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program. For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements.

We are not proposing any changes to these policies.

D. Administrative Requirements

1. Proposed Requirements Regarding QualityNet Account and Security Administrator

a. Background for the CY 2014 and CY 2015 Payment Determinations

A QualityNet account is required to submit quality measure data to the QualityNet Web site via a Web-based tool and, in accordance with CMS policy, a QualityNet security administrator is necessary to set-up such an account for the purpose of submitting this information to the QualityNet Web site. In previous rulemaking, we referred to this role as the QualityNet administrator; we are referring to this role in this rulemaking as the QualityNet security administrator, which emphasizes its security function and aligns terminology for the ASCQR Program with the

Hospital IQR and OQR Programs. While the main purpose of a QualityNet security administrator is to serve as a point of contact for security purposes for quality reporting programs, we believe from our experience that a QualityNet security administrator typically fulfills a variety of tasks related to quality reporting, such as creating, approving, editing, and terminating QualityNet user accounts within an organization, and monitoring QualityNet usage to maintain proper security and confidentiality measures. Thus, we highly recommend that ASCs have and maintain a QualityNet security administrator.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53638 through 53639), we did not require that ASCs do so for the CY 2014 payment determination because ASCs are not required to submit data directly to the quality data warehouse for the CY 2014 payment determination (76 FR 74504) and we do not want to unduly burden ASCs by requiring ASCs to have a QualityNet security administrator. We note that a QualityNet account is not necessary to access information that is posted to the QualityNet Web site, such as specifications manuals and educational materials.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74504 through 74509), for the CY 2015 payment determination, we require ASCs to submit some quality measure data via an online tool located on the QualityNet Web page. As set forth in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53638 through 53639), to enter these data into our data system, we require that ASCs identify and register a QualityNet security administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site. Because submission of these data is not required until the July 1, 2013 to August 15, 2013 time period, we require that ASCs have a QualityNet security administrator at the time ASCs submit Web-based measure data in 2013 for the CY 2015 payment determination, which is no later than August 15, 2013. ASCs may have a QualityNet security administrator prior to this date, but we do not require that ASCs do so.

We noted that there are necessary mailing and processing procedures that must be completed in order to have a QualityNet security administrator which are separate from completion of the forms by the ASC that can require significant time to complete. We strongly cautioned ASCs to not wait until the deadline to apply; instead, we recommended allowing a minimum of 2 weeks, and strongly suggested allowing additional time prior to the deadline to submit required documentation in case of unforeseen issues. Because ASCs will need a QualityNet security administrator only to have the ability to set up a user account for the purpose of submitting such measure data once a year, we do not require that ASCs maintain a QualityNet security administrator after the entry of their data via an online tool located on the QualityNet Web site in 2013 for the CY 2015 payment determination.

We also note that QualityNet users must complete a user enrollment process, which is part of the registration process, to ensure access to the Secure QualityNet Portal beginning July 1, 2013. Portal access will be required for ASCs submitting data under the ASCQR Program using an online tool located on the QualityNet Web site.

b. Proposed Requirements for the CY 2016 Payment Determination and Subsequent Years

For the CY 2016 payment determination and subsequent years, we are proposing that, similar to the requirement for the CY 2015 payment determination, ASCs would be required to have a QualityNet security administrator for the purposes of setting up a QualityNet account for the purpose of entering data via an online tool located on the QualityNet Web site if this had not been completed previously or no current user accounts were available. If an ASC does not already have a QualityNet account, the facility would need to identify and register a QualityNet security administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site. A QualityNet security administrator is not required for submitting data, a QualityNet security administrator is required to set up user accounts and for security purposes; a current user account is required for submitting data. Thus, an ASC would need to acquire a QualityNet security administrator only if no current QualityNet account existed for the ASC. An ASC would be required to have an active account by any specified data entry deadline. For example, the deadline would be August 15, 2014 for the CY 2016 payment determination. Although we highly recommend that ASCs have and maintain a QualityNet security administrator, we believe that requiring an ASC to maintain a QualityNet administrator throughout the year would unnecessarily increase burden on ASCs.

As noted previously, there are necessary mailing and processing procedures for having a QualityNet security administrator assigned by CMS separate from completion of the forms by the ASC that can require significant time to complete and we strongly caution ASCs to not wait until any data entry deadline to apply. While we previously recommended allowing a minimum of 2 weeks, based upon recent experience, we strongly suggest allowing 4 to 6 weeks prior to any data submission deadline to submit required documentation for processing and in case of unforeseen issues. Also, QualityNet users must complete a user enrollment process, which is part of the registration process, to ensure access to the Secure QualityNet Portal. Portal access will be required for ASCs submitting data under the ASCQR Program to meet CMS IT security requirements. The legislative source for this requirement originates in the Federal Information Security Management Act of 2002 which was amended by the Cybersecurity Act of 2012. The Document Library on the *http://www.idmanagement.gov* Web site contains documentation related to identity management including the Federal Identity, Credential and Access Management (FICAM) Roadmap and Implementation Guidance (version 2, 12/08/2011).

We invite public comment on these proposals.

2. Proposed Requirements Regarding Participation Status

a. Background for the CY 2014 Payment Determination and Subsequent Years

We finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516) a policy to consider an ASC as participating in the ASCQR Program for the CY 2014 payment determination if the ASC includes Quality Data Codes (QDCs) specified for the ASCQR Program on their CY 2012 claims relating to the finalized measures.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53639 through 53640), we stated that once an ASC submits any quality measure data, it would be considered to be participating in the ASCQR Program. Further, once an ASC submits any quality measure data and is considered to be participating in the ASCQR Program, an ASC would continue to be considered participating in the ASCQR Program, regardless of whether the ASC continues to submit quality measure data, unless the ASC withdraws from the Program by indicating on a participation form that it is withdrawing, as discussed below.

For example, if an ASC includes any QDCs on its claims for the CY 2014 payment determination, it would be considered participating in the ASCQR Program for the CY 2014 payment determination and for each subsequent year's payment determination unless the ASC withdraws.

Likewise, if an ASC did not submit any QDCs for the CY 2014 payment determination, but submitted quality measure data for the CY 2015 payment determination, the ASC would be considered participating in the ASCQR Program starting with the CY 2015 payment determination and continuing for each subsequent year's payment determination unless the ASC withdraws from the ASCQR Program.

We considered whether to require that an ASC complete and submit a notice of participation form for each year's payment determination to indicate that the ASC is participating in the ASCQR Program as we require for hospitals, but decided against this approach because we were concerned about the burden on ASCs. We believe these requirements will reduce burden on ASCs while accomplishing the purpose of notifying us of an ASC's participation in the ASCQR Program.

We stated that any and all quality measure data submitted by the ASC while participating in the ASCQR Program could be made publicly available. This policy allows us to provide information on the quality of care provided to Medicare beneficiaries which promotes transparency.

Once an ASC submits quality measure data indicating its participation in the ASCQR Program, an ASC must complete and submit an online form indicating withdrawal in order to withdraw from the ASCQR Program. This form will be located on the QualityNet Web site starting in July 2013. We also require that an ASC indicate on the form the initial payment determination year to which the withdrawal applies. We established a different process for ASCs to withdraw from participation than the process we established for an ASC to participate in the ASCQR Program because of the payment implications of withdrawal. We stated that, in withdrawing from the ASCQR Program, the ASC would incur a 2.0 percentage point reduction in its annual payment update for that payment determination year and any subsequent payment determinations in which it is withdrawn.

We stated that we will not make quality measure data publicly available for that payment determination year and any subsequent payment determinations for which the ASC is withdrawn from the ASCQR Program.

We established that an ASC would continue to be deemed withdrawn unless the ASC starts submitting quality measure data again. Once an ASC starts submitting quality measure data, the ASC would be considered participating unless the ASC withdraws, as discussed above. We believe that these policies reduce the burden on ASCs by not having to notify us as to when they are participating.

We established that an ASC can withdraw from the ASCQR Program at any time up to August 31, 2013 for the CY 2014 payment determination. We anticipated that this will be the latest date possible to allow an ASC to withdraw before payment determinations affecting CY 2014 payment are made. We established that an ASC can withdraw from the ASCQR Program at any time up to August 31, 2014 for the CY 2015 payment determination. We clarify here that these deadlines include August 31st for each respective year.

We stated that these program requirements would apply to all ASCs designated as open in the CASPER system before January 1, 2012 for the CY 2014 payment determination. Because ASCs were not required to include QDCs on claims until October 2012 for the CY 2014 payment determination, an ASC designated as open in the CASPER system before January 1, 2012 was operating for at least 10 months before having to report any data. We believe this is a sufficient amount of time for ASCs to be established to report quality data for the CY 2014 payment determination.

For the CY 2015 payment determination, we established that program requirements would apply to all ASCs designated as open in the CASPER system for at least 4 months prior to January 1, 2013. We believe that this date and length of operations experience would provide new ASCs sufficient time before having to meet quality data reporting requirements after the ASCQR Program's initial implementation year.

b. Proposed Requirements for the CY 2016 Payment Determination and Subsequent Years

For the CY 2016 payment determination and subsequent years, we are proposing that an ASC can withdraw from the ASCQR Program at any time up to and including August 31 of the year preceding a payment determination. We anticipate that this will be the latest date possible to allow an ASC to withdraw before payment determinations affecting the next calendar year's payment are made. Thus, for example, for the CY 2016 payment determination, an ASC would be able to withdraw from the ASCQR Program at any time up to and including August 31, 2015. Once an ASC has withdrawn for any payment determination year, it would have a 2.0 percentage point reduction in their annual payment update and it would not be possible to reinstate participation status for that year.

For the CY 2016 payment determination and subsequent years, we are proposing that all program requirements would apply to all ASCs designated as open in the CASPER system at least 4 months prior to the beginning of data collection for a payment determination. Thus, for the CY 2016 payment determination, data collection begins with January 1, 2014 services; these program requirements would apply to all ASCs designated as open in the CASPER system for at least 4 months prior to January 1, 2014 (that is, an open date of September 1, 2013 or earlier). We believe that this date and length of operations experience would provide any new ASCs sufficient time before having to meet quality data reporting requirements.

We invite public comment on these proposals.

3. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures for the CY 2014 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74496 through 74511), we adopted five claims-based measures for the CY 2014, CY 2015, and CY 2016 payment determinations and subsequent years. We also finalized that, to be eligible for the full CY 2014 ASC annual payment update, for the claims-based measures, an ASC must submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims (76 FR 74515 through 74516). Further, we finalized the data collection period for the CY 2014 payment determination, as the Medicare fee-for-service ASC claims submitted for services furnished between October 1, 2012 and December 31, 2012. ASCs will add the appropriate QDCs on their Medicare Part B claims, using the Form CMS–1500 or associated electronic data set submitted for payment, to submit the applicable quality data. A listing of the QDCs with long and short descriptors is available in Transmittal 2425, Change Request 7754

released March 16, 2012 (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Transmittals-Items/ASC-CR7754-R2425CP.html*). Details on how to use these codes for submitting numerator and denominator information are available in the ASCQR Program Specifications Manual located on the QualityNet Web site (*https://www.QualityNet.org*).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53640), we adopted a policy that claims for services furnished between October 1, 2012 and December 31, 2012 would have to be paid by the administrative contractor by April 30, 2013 to be included in the data used for the CY 2014 payment determination. We believe that this claim paid date allows ASCs sufficient time to submit claims while allowing sufficient time for CMS to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68497 through 68498), we finalized a data collection and processing period for the CY 2015 payment determination and subsequent years. For the CY 2015 payment determination and subsequent years, an ASC must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. The data collection period for such claims-based quality measures is the calendar year 2 years prior to a payment determination year. The claims for services furnished in each calendar year have to be paid by the administrative contractor by April 30 of the following year of the ending data collection time period to be included in the data used for the payment determination year. Thus, for example, for the CY 2015 payment determination, the data collection period is claims for services furnished in CY 2013 (January 1, 2013 through December 31, 2013) which are paid by the administrative contractor by April 30, 2014.

We are not proposing any changes to these policies.

4. Proposed Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

a. Background for the CY 2014 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized our proposal that data completeness for claims-based measures for the CY 2014 payment determination be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641), we finalized our policy for the CY 2014 and CY 2015 payment determination years that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe that 50 percent is a reasonable minimum threshold for the initial implementation years of the ASCQR Program because ASCs are not familiar with how to report quality data under the ASCQR Program and because many ASCs are relatively small and may need more time to set up reporting systems. We stated in that final rule that we intend to propose to increase this percentage for subsequent years' payment determinations as ASCs become more familiar with reporting requirements for the ASCQR Program.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641), we stated that, because private payers would not have QDCs in their required HCPCS data files until January 1, 2013, claims with QDCs received prior to January 1, 2013 could be rejected for invalid codes. Because it is not possible for ASCs to submit differing codes on primary versus secondary payer claims for at least some payers, we specified that only claims where Medicare is the primary payer—not the secondary payer—will be used in the calculation of data completeness for the CY 2014 payment determination.

We also finalized our proposal in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68498 through 68499) that data completeness for claims-based quality measures for the CY 2015 payment determination and subsequent years will be determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims (where Medicare is the primary or secondary payer) that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims for the CY 2015 payment determination and subsequent years. We made this change based on the fact that private payers had QDCs in their required HCPCS data files beginning January 1, 2013.

b. Proposed Requirements for the CY 2016 Payment Determination and Subsequent Years

For the CY 2016 payment determination and subsequent years, we are proposing to continue our policy that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe that 50 percent is a reasonable minimum threshold for the initial implementation years of the ASCQR Program. Because ASCs cannot re-submit claims for the sole purpose of adding QDCs (such claims are rejected by administrative contractors as duplicate claims), we believe maintaining this minimum as the program matures is reasonable. We intend to propose to increase this percentage for future payment determinations as ASCs, administrative contractors, and billing clearing houses become more familiar with reporting requirements for the ASCQR Program and the program itself becomes more established.

As finalized in the FY 2013 IPPS/LTCH PPS final rule, data completeness for claims-based quality measures will be determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims (where Medicare is the primary or secondary payer) that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims for the CY 2015 payment determination and subsequent years.

In our initial implementation of claims-based measures, we determined that some ASCs have relatively small numbers of Medicare claims. Thus, for the CY 2016 payment determination and subsequent years, we are proposing a minimum case volume of 240 Medicare claims (primary plus secondary payer) per year (which is an average of 60 per quarter). ASCs that have fewer than 240 Medicare claims per year during a reporting period for a payment determination year would not be required to participate in the ASCQR Program for the subsequent reporting period for that subsequent payment determination year. For example, if an ASC had 200 Medicare claims during the calendar year of January 1, 2013 to December 31, 2013 (data submitted on claims during this year would be applied to CY 2015 payment determinations), the ASC would not be

required to participate in the ASCQR Program for the CY 2016 payment determination (which would use data submitted on claims during the January 1, 2014 to December 31, 2014 calendar year). We are proposing a minimum case threshold to exempt smaller facilities where program implementation can be overly burdensome. We have selected 240 Medicare claims per year because 10 percent of ASCs have less than 240 Medicare claims per year so this policy would exempt only those ASCs with the fewest number of Medicare claims. If an ASC exceeds this 240 Medicare claim threshold in any given calendar year, the ASC would be required to participate in the ASCQR Program the subsequent calendar year and would be subject to all program requirements.

We invite public comment on this proposal.

5. Proposed Requirements for Data Submitted Via a CMS Online Data Submission Tool

a. Background for the CY 2015 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period, we finalized two measures with data submission required using an online measure submission Web page available at *http://www.qualitynet.org* beginning with the CY 2015 payment determination: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures (76 FR 74509). In that final rule with comment period, we finalized that, for the CY 2015 payment determination, ASCs would report data for these two measures between July 1, 2013 and August 15, 2013 for services furnished between January 1, 2012 and December 31, 2012.

b. Proposed Requirements for the CY 2016 Payment Determination and Subsequent Years for Measures Currently Finalized

For the CY 2016 payment determination and subsequent years, we are proposing for the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures for which data will be submitted via a using an online data submission tool available on *http://www.qualitynet.org,* that the data collection time periods would be for services furnished during the calendar year two years prior to the payment determination year and that data would be submitted during the January 1 to August 15 time period in the year prior to the payment determination. Thus, for the CY 2016 payment determination, the data collection time period for these measures would be calendar year 2014 (January 1, 2014 to December 31, 2014) and the data submission time period would be January 1, 2015 to August 15, 2015. We are proposing these changes to increase the timeframe for allowing data submission for these measures and to align the data collection time periods for the claims-based and Web-based measures. This alignment has the additional benefit of providing more current data for these Web-based measures for a payment determination and would prevent the need for retrospective data collection by ASCs which can be burdensome.

Under this proposal, no data would be collected for calendar year 2013 (January 1, 2013 to December 31, 2013) for the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures because the CY 2015 payment determination will use data from services performed in the January 1, 2012 to December 31, 2012 time period and, under our proposal, the CY 2016 payment determination would use data from services performed in January 1, 2014 to December 1, 2014.

We invite public comment on these proposals.

c. Proposed Requirements for the CY 2016 Payment Determination and Subsequent Years for Proposed New Measures With Data Submission Via a CMS Web-Based Tool

We are proposing to adopt four additional chart-abstracted measures for the ASCQR Program and proposing that aggregate data (numerators, denominators, and exclusions) on all ASC patients would be collected via an online Web-based tool that would be made available to ASCs via the QualityNet Web site.

These measures are: (1) Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures; (2) Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients; (3) Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (4) Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We describe our timeframes and process for measure specifications in section XV.B.5. of this proposed rule.

We wish to clarify that, while we have referred to measures where data are submitted via a Web-based tool on a CMS Web site under our quality data reporting programs by the type of measure, that is, structural measures (measures concerned with attributes of where care occurs, such as material resources, human resources, and organizational structure [15]), not all quality measures where data are submitted via a Web-based tool on a CMS Web site are structural measures. For example, the four proposed new measures proposed are not structural measures. Thus, we have refined our terminology and now refer to the mode of data submission, Web-based, rather than the type of measure.

We are proposing that data collection and reporting for these measures would begin with the CY 2016 payment determination.

Additionally, we are proposing for these measures, and any future measures for the ASCQR Program where data is submitted via a using an online measure submission Web page available on *http://www.qualitynet.org,* that beginning with the CY 2016 payment determination:

- The data collection time period would be the calendar year (January 1 to December 31) 2 years prior to the affected payment determination year, and;
- Data collected would be submitted during the time period of January 1 to August 15 in the year prior to the affected payment determination year.

Thus, for the CY 2016 payment determination, the data collection time period would be January 1, 2014 to December 31, 2014 and the data submission time period for the collected data would be January 1, 2015 to August 15, 2015. These proposals are in alignment with proposals in section XV.D.5. of this proposed rule regarding data collection and submission time frames for measures already adopted for the ASCQR Program where data is submitted via an online data submission tool available on *http://www.qualitynet.org.*

We invite public comment on these proposals.

6. Proposed Data Submission Requirements for a Measure Reported Via the National Healthcare Safety Network (NHSN) for the CY 2016 Payment Determination

a. Background for the CY 2016 Payment Determination

For the CY 2016 payment determination, we finalized the adoption of the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), a process of care,

[15] Maintz, J. Defining and Classifying Clinical Indicators for Quality Improvement, Inter J Quality Health Care (2003) 15(6), 523–530.

healthcare-associated infection (HAI) measure, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74510). We specified that data collection for the influenza vaccination measure would be via the NHSN from October 1, 2014 to March 31, 2015 and that details for data submission would be made in future rulemaking.

b. Proposed Requirements for the CY 2016 Payment Determination

We are proposing to use the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site (for detailed enrollment (*http://www.cdc.gov/nhsn/ambulatory-surgery/enroll.html*), set-up (*http://www.cdc.gov/nhsn/ambulatory-surgery/setup.html*), and reporting (*https://sdn.cdc.gov*; data certificate required for this site) procedures. We believe that ASCs would know and be comfortable with these procedures because these procedures are already used by many ASCs to fulfill State-mandated reporting of HAI data through the NHSN in at least 17 States.

We are proposing that ASCs would have until August 15, 2015 to submit their 2014–2015 influenza season data to NHSN. We are proposing an August 15, 2015 deadline because this date is the latest date possible for data entry that will provide sufficient time for CMS to make the CY 2016 payment determinations. Further, this date aligns the data entry deadline with the deadline for the measures entered via the CMS online tool. We believe this data submission deadline allows ASCs to have sufficient time to collect and compile the necessary data while taking into account ASCQR Program considerations.

We invite public comment on these proposals.

7. ASCQR Program Validation of Claims-Based and CMS Web-Based Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641 through 53642), consistent with other CMS quality reporting programs, we did not require validation of claims-based measures (beyond the usual claims validation activities conducted by our administrative contractors) or structural (Web-based) measures for the ASCQR Program. We also do not require validation of claims-based or Web-based measures under the Hospital IQR and OQR Programs.

We noted that with regard to the current ASCQR Program claims-based measures, the number of events expected to be reported is small because most of the measures are for adverse or rare events. In this situation, any random selection of cases would require a burdensome sample size. Further, we expect the accuracy for reported adverse events to be high. We stated that, because we do not believe at this time that any results that could be obtained justify the burden associated with a data validation process which would necessitate an independent validation effort, we also are not requiring a data validation process for our current claims-based measures, and we continue to believe so.

We stated that as we gain more experience with the ASCQR Program, we will reassess whether a data validation process for claims-based and measures where aggregate data is reported via an online tool is needed. At this time, we believe that it would be overly burdensome to validate the reported data given the inexperience that ASCs have with reporting quality data to CMS coupled with the low incidence of cases for the claims-based measures.

8. Extraordinary Circumstances Extensions or Waivers for the CY 2014 Payment Determination and Subsequent Years

a. Background

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal to not penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643), we established procedures for extraordinary circumstance extension or waiver requests for the submission of information required under the ASCQR Program. We refer readers to that rule for a complete discussion of the process.

b. Proposed Additional Criterion for Extraordinary Circumstance Waivers or Extensions for CY 2014

We are proposing that starting in CY 2014 we may grant a waiver or extension to ASCs for data submission requirements if we determine that a systematic problem with one of our data collection systems directly or indirectly affected the ability of ASCs to submit data. Because we do not anticipate that such systematic errors will happen often, we do not anticipate granting a waiver or extension on this basis frequently. If we make the determination to grant a waiver or extension, we are proposing to communicate this decision through listserv notice and posting via our QualityNet Web site (*https://www.qualitynet.org*) as we have done in the past with CMS-issued waivers where a geographic location was affected by adverse weather.

We invite public comment on this proposal.

9. ASCQR Program Reconsideration Procedures for the CY 2014 Payment Determination and Subsequent Years

We have established similar processes by which participating hospitals can submit requests for reconsideration of quality reporting program payment determinations for the Hospital IQR Program and the Hospital OQR Program. We believe these reconsideration processes have been effective in the hospital quality reporting programs and such a process would be effective for ASC quality reporting. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 56344), we adopted an informal reconsideration process for the ASCQR Program for the CY 2014 payment determination and subsequent years modeled after the reconsideration processes we implemented for the Hospital IQR and Hospital OQR Programs. We refer readers to that rule for a complete discussion of our procedures.

We are not proposing any changes to this informal reconsideration process. However, we want to clarify some aspects of the informal reconsideration review process that we established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 to 53644). As we stated in that rule, we intend to complete any reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration. For those ASCs that submit a reconsideration request, the reconsideration determination would be the final ASCQR Program payment determination. For those ASCs that do not submit a reconsideration request or do not submit a reconsideration request as specified in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644), for example, the request was not submitted by the deadline, the CMS determination would be the final payment determination. There would be no appeal of any final ASCQR Program payment determination.

XVI. Proposed Changes to the Conditions for Coverage (CfCs) for Organ Procurement Organizations (OPOs) (42 CFR Part 486, Subpart G)

A. Background

The Organ Procurement Organization Certification Act of 2000 (section 701 of Pub. L. 106–505) amended section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and directed the Secretary to establish regulations governing the certification and/or recertification of Organ Procurement Organizations (OPOs). Among other things, section 371(b)(1)(D)(ii) of the Public Health Service Act, as amended by section 701 of Public Law 106–505, requires that regulations be established for the certification and/or recertification process, which (1) ''rely on outcome and process performance measures that are based on empirical evidence obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations,'' and (2) ''use multiple outcome measures as part of the certification process.'' Payment under the Medicare and Medicaid programs for organ procurement costs may only be made if, among other requirements, the OPO is certified or recertified as meeting the standards to be a qualified OPO under section 371(b) of the Public Health Service Act and meets the performance-related standards prescribed by the Secretary, as provided for in section 1138(b) of the Social Security Act.

The final rules implementing these statutory requirements and setting out the Conditions for Coverage (CfCs) for OPOs (OPO CfCs) were published in the **Federal Register** on May 31, 2006 (71 FR 30982). The OPO CfCs are codified at 42 CFR Part 486 and set forth the certification and recertification processes for OPOs. OPOs are required to meet their CfCs, which include both outcome and process performance measures. We refer readers to 42 CFR 486.316 for the compliance requirements for recertification and 42 CFR 486.318 for the three outcome measures.

In general, with the exception of OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions, the three outcome measures are: (1) A donation rate of eligible donors as a percentage of eligible deaths; (2) an observed donation rate as compared to the expected donation rate; and (3) a yield measure, which requires that two of the following three outcome measures be met: (i) The number of organs transplanted per standard criteria donor, (ii) the number of organs transplanted per expanded criteria donors, and (iii) the number of organs used for research per donor. For OPOs that operate exclusively in noncontiguous States, Commonwealths, Territories, and possessions, the three outcome measures are: (1) A donation rate of eligible donors as a percentage of eligible deaths; (2) an observed donation rate as compared to the expected donation rate; and (3) a yield measure, which requires that two of the following three outcome measures be met: (i) The number of kidneys transplanted per standard criteria donor; (ii) the number of kidneys transplanted per expanded criteria donors; and (iii) the number of organs used for research per donor. All of the yield measures include pancreata used for islet cell transplantation as required by section 371(c) of the Public Health Service Act (42 U.S.C. 273(c)). The first and third outcome measures are compared to a national mean. The second outcome measure is calculated by the Scientific Registry of Transplant Recipients (SRTR).

B. Proposed Regulatory Changes

We are proposing to modify the requirements in § 486.316(a)(1) and (b) and the introductory text of § 486.318(a) and (b) of the regulations so that all of the OPOs must meet two out of the three outcome measures to be recertified. We have become concerned about the requirement to automatically decertify OPOs if they fail to meet all three of the outcome measures. We now believe that the requirement that each OPO meet all three outcome measures as set forth in § 486.318 is unnecessarily stringent. For that reason, we are proposing to modify the outcome measure requirement so that OPOs would be required to meet two of the three outcome measures.

The majority of all of the OPOs are meeting all three of the outcome measures. From our experience with OPOs, we have observed that many of the OPOs that are failing to meet all three outcome measures are meeting two of the three measures and are in compliance with all of the other requirements in the OPO CfCs; that is, the process performance measures set forth at §§ 486.320 through 486.348. We believe these OPOs are performing satisfactorily and should not be decertified based solely on their failure to meet one outcome measure. This belief is based not only on our observation and monitoring of these OPOs' performance, but also on some concerns with the outcome measures.

From the feedback we have received from the OPO community, there may be some variance in how OPOs are determining the ''eligible deaths'' in their donation service area (DSA), which is the denominator in the first outcome measure. Various members of the OPO community have indicated that the same donor could be counted as an eligible donor by one OPO, but not another OPO. This is apparently due to differences in how the definition of ''eligible death'' is being clinically interpreted and implemented. Another reason for this variance could be how the determination is made. One member of the OPO community stated that, in one OPO, that determination may be made by a group of clinical staff, while in another, it is made by the data entry person. Therefore, we are concerned that this apparent variance may be adversely affecting the performance of some OPOs on the outcome measures.

We also are concerned that the current measures may not be accurately allowing for adjustment of various factors. OPOs' DSAs vary substantially in their demographics. For example, the first of the possible three yield outcome measures involves standard criteria donors. However, many individuals in the OPO community have indicated that there is a considerable difference between standard criteria donors (SCDs) around the country and that this could explain at least some of the differences in some of the OPOs' yield measures. Because a SCD is anyone who meets the eligibility criteria for an eligible donor and does not meet the criteria to be an expanded criteria donor or a donor after cardiac death, the demographics of an OPO's DSA could have a significant impact on the organ yield that could reasonably be expected in that DSA. For example, if a particular DSA has an older potential donor population or one that is typically not as healthy, this could significantly impact the organ yield in that DSA as compared to a DSA with a population of generally more healthy individuals.

We also have received anecdotal reports that OPOs may be making clinical decisions based on their assessment of their own performance on the outcome measures. In particular, there may have been cases when OPOs did not pursue certain potential donors with multiple comorbidities because they believed that they would only be able to procure one or two organs from that potential donor. If an OPO is concerned about its performance on the yield measures specified under § 486.318(a)(3) and (b)(3), it may be advantageous to its performance on the yield measures to forgo a potential donor rather than procure only one organ and worsen its performance on the yield measures. This would result in

not only one potentially transplantable organ being averted, but consequently a potential transplant recipient not receiving a transplant. This could have a significant impact on the potential transplant recipient waiting for transplants nationwide. This is especially problematic in the case of extra-renal organs for which there is no viable alternative to an organ transplant.

We are proposing to hold the OPOs accountable for meeting two out of three current outcome measures. We believe this will avoid the automatic decertification of OPOs that are performing satisfactorily. Therefore, we are proposing to revise paragraphs (a)(1) and (b) of § 486.316 and the introductory text of paragraphs (a) and (b) of § 486.318 of the regulations to require that OPOs meet at least two out of the three outcome measures instead of the requirement to meet all three outcome measures.

In addition to soliciting public comments on the proposals we discuss above, we are soliciting public comments on the current outcome measures in the OPO CfCs, as well as public comments on any other potential empirically based outcome measures for OPOs that might be used in the future. We would especially appreciate public comments on the new yield measure that is produced by the SRTR and is being used by the Organ Procurement and Transplantation Network (OPTN). The OPTN recently adopted this new yield measure that calculates the expected number of organs transplanted for each donor based on multiple donor risk factors. The measure uses more extensive risk factors that mitigate the differences in the donor pool of the each DSA. This allows an OPO's performance to be measured in terms of the expected outcomes for the DSA based upon the expected outcomes for individual donors within the DSA and not against a national average.

When comparing OPOs currently identified to be below expected performance levels by the OPTN matrix and the OPOs identified as below expected performance levels by the CMS measures, we have noted that the lists are not the same. If the new OPTN measure is a more accurate reflection of performance as measured by the organs transplanted for each donor in each individual DSA (as is accepted by the HRSA and the OPO community), this could mean that we may take inappropriate enforcement action when using the current yield measure. Therefore, we are specifically soliciting public comments on this new OPTN yield measure. Specific details on the risk adjustment models used for this measure are located on the SRTR Web site at: *http://www.srtr.org/csr/current/Tech_notes.aspx.*

In summary, we are proposing to revise §§ 486.316 and 486.318 of our regulations by modifying the current outcome measures requirement to require that OPOs must meet two out of the three outcome measures instead of all three outcome measures.

XVII. Proposed Revisions of the Quality Improvement Organization (QIO) Regulations

A. Legislative History

The Utilization and Quality Control Peer Review Program was originally established by sections 142 and 143 of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Pub. L. 97–248). The name of the individual organizations covered under the program was ''Peer Review Organizations.'' In a final rule with comment period published in the **Federal Register** on May 24, 2002 (67 FR 36539), we revised the regulatory references to these organizations to ''Quality Improvement Organizations'' (QIOs)—without changing the definition or functions of the QIOs—to reflect the program's shift from a compliance-oriented focus to one emphasizing quality improvement. There have been a number of amendments to the QIO statute over the years, but they have not resulted in any substantial changes in how the program operates. However, in section 261 of the recently enacted Trade Adjustment Assistance Extension Act of 2011 (TAAEA) (Pub. L. 112–40), Congress authorized numerous changes to the original legislation to modernize and improve the QIO Program and included additional flexibility for the Secretary in the administration of the QIO Program. This legislation also updated the nomenclature from the Peer Review Organization Program to the QIO Program and included amendments to update the terminology of the program (replacing ''peer review organization'' and ''utilization and quality control peer review organization'' with ''quality improvement organization'' in relevant provisions of the Act.)

Specifically, section 261 of the TAAEA increased the flexibility available to the Secretary by updating the statutory definition of the organizations that can contract with CMS as QIOs (as described in section 1152 of the Act), changing certain contract terms and processes by which the Secretary contracts with QIOs (as described in section 1153 of the Act), and broadening the Secretary's authority to delineate the scope of work for QIOs (as described in section 1154 of the Act).

The regulations that implement sections 1152 and 1153 of the Act are codified at 42 CFR Part 475; Subpart C of Part 475 includes provisions that specifically govern the types of organizations eligible to become QIOs. The regulations that implement section 1154 of the Act and much of the work performed by QIOs are codified at 42 CFR Part 476. Section 1154 of the Act states that much of the work QIOs will perform is subject to the terms of their contracts with CMS. We note that, consistent with this provision, the contracts and requests for proposals used to contract with QIOs include significant detail on the work performed by the QIOs.

B. Basis for Proposals

Section 261 of the TAAEA eliminated certain limitations specified in sections 1152 and 1153 of the Act that appear in several existing provisions in Part 475. In order to eliminate these limitations in the regulations and fully utilize the flexibility provided as a result of the statutory changes, we are proposing regulatory changes to implement the statutory amendments. These changes involve, among other things, changing the eligibility standards for an entity to be awarded a QIO contract and defining specific terms that will be used to describe QIOs and their quality improvement work. We are proposing to change the terminology related to the geographic area in which a QIO must perform its different functions. As the statute authorizes, the QIO area can now be any geographic area CMS believes will be most effective in accomplishing its goals for the QIO contract. We also are proposing to revise provisions regarding the eligibility of a health care facility association to be a QIO and to eliminate an obsolete provision at § 475.106 regarding the eligibility of payor organizations to be QIOs. The statutory amendments also include a change in the contract period for a QIO, extending it from 3 to 5 years. Although we did not previously update this regulation with a prior statutory change in the QIO contract term from 2 years to 3 years, we are now including the 5-year time period in the proposed rule as a technical correction in order to bring the regulations up to date with the amended statutory timeframe. We believe that these changes would be instrumental in improving aspects of the QIO's review activities and would enable us to improve the program by ensuring that QIOs are better able to meet the needs of Medicare beneficiaries. The specific proposed

changes and corrections are explained in more detail in the following sections.

QIOs work at the grassroots level of American health care delivery systems in all 50 States, the District of Columbia, and most U.S. Territories in order to improve care for Medicare beneficiaries. QIOs originally reviewed Medicare services to determine whether they were reasonable and medically necessary, met professionally recognized standards of care, and were provided in the appropriate setting. However, the QIO contract has evolved over the course of the years as the literature supports the concept that defects in the health care process are rarely related to the performance of one individual but to a system of care with multiple opportunities for failure. Attempts to improve quality through inspection methods, that is, by performing one chart review at a time, are less likely to yield the systemic improvements in care for Medicare beneficiaries that can come from analyzing data in order to identify problems, developing a plan of action, monitoring the result through data driven processes, and making changes as needed based on those results.

The qualifications and expertise required to execute these quality improvement initiatives have evolved to now include expertise from disciplines such as physicians, nurses, other clinicians, health care leaders, experts in statistics and health care system reengineering, and many other kinds of professionals. We intend to interpret our proposed regulation so as not to prohibit the use of professionals in the health care industry that are not licensed physicians or certified practitioners. We recognize/anticipate that these other professionals may offer valuable insight to QIOs on ways to enhance the performance of their QIO functions, as well as provide services designed to help QIOs maximize their impact. We propose to adopt this approach to further our goal that the regulations under 42 CFR Part 475 reflect a multidisciplinary approach to the performance of QIOs. Therefore, the proposed standards here would not be a barrier to the inclusion of any other nonphysician or nonpractitioner professional that CMS or the QIO deems appropriate for the successful performance of QIO functions. Patients and their families also play a critical role in the success of quality improvement initiatives. Amendments to the Act made by the TAAEA would accommodate the evolution of quality improvement and would allow CMS the flexibility to expand the types of organizations eligible to provide multi-disciplinary support in quality improvement. We seek with this proposal to ensure that the regulations governing QIO eligibility reflect the increased flexibility afforded by the TAAEA. This will help us ensure that we can administer the QIO Program in a manner that reflects contemporary practices and allows us to include the appropriate individuals and entities in working toward improving care processes.

As described in section 1154 of the Act, QIOs perform many specific review functions that are necessary to ensure the quality of care provided to Medicare beneficiaries. The addition to section 1154 of subparagraph (a)(18) by the TAAEA explicitly provides the Secretary with the broad authority to require that QIOs perform any additional activities the Secretary determines may be necessary for the purposes of improving the quality of Medicare services. Based on this authority, QIOs will, as a general matter, be required to represent CMS as ''change agents'' that work at local levels in their individual QIO geographic areas. Through the contracting process, different QIOs might now be required to work on one or more different tasks; that is, all QIOs might no longer be required to handle the complete and broad range of QIO activities within their geographic areas but to focus on particular tasks of QIO work. For example, QIOs might be required to offer to a variety of stakeholders the knowledge and resources for improving health quality, efficiency, and value designed to improve the care provided to Medicare beneficiaries. Stakeholders might include providers, practitioners, patients, and others who are interested in improving care.

As under the current program, QIOs will be required to base their work on clinical evidence and some may be required to generate reliable data about clinical performance. QIOs may also serve as independent, objective, and collaborative partners that support CMS' mission to improve health care quality in the Medicare program (which, in turn, has the potential to greatly benefit the broader health care community) by leveraging the best efforts of all health care stakeholders, including patients and their families. While the goal of the QIOs is to benefit Medicare beneficiaries, the work of the QIOs may also, as a secondary matter, benefit other patients and residents who receive medical care. In this context, we are seeking to ensure that the regulations governing QIO eligibility reflect contemporary practices and include those that can help to improve care processes for Medicare beneficiaries. We are proposing to do so by removing restrictions that are no longer statutorily mandated and including requirements that reflect the current goals of the QIO program.

One such contemporary practice is the inclusion of patients and families in health care quality improvement. As a result, we have added to the QIO requirements a new focus on patient and family engagement and patient and family inclusion in quality improvement initiatives.

We believe that the TAAEA legislation allows us a great deal of flexibility in how we restructure the work that QIOs perform and the types of organizations qualified to perform that work. We intend to continually examine methods for providing care to beneficiaries in a way that maximizes efficiency, eliminates waste, decreases harm, lowers costs through improvement, and engages patients more effectively. One way to continue improving the quality, efficacy, and efficiency of care in the Medicare program is to reconsider how QIOs provide services to determine whether the current longstanding contract structure and eligibility requirements best fit the continually evolving science related to driving quality improvement. The changes we are proposing are intended to ensure that we have the flexibility we need to reconsider certain aspects of the QIO program structure in response to experience and changes in research findings and the health care community's approach to quality improvement.

The regulatory proposals here focus on the primary functional responsibilities of a QIO as a basis for determining eligibility. These are case review (which includes the statutory minimum standards) and quality improvement initiatives. We believe that the proposed eligibility and contracting standards for QIOs focus on the necessary minimum requirements for successful operation of the QIO Program.

C. Proposed Changes to the Nomenclature and Regulations Under 42 CFR Parts 475 and 476

In this proposed rule, we set forth proposals for updating the nomenclature and the definition of physician in both 42 CFR Parts 475 and 476 and for the partial deletion and revision of the regulations under 42 CFR Parts 475. Currently, Part 475 includes definitions and standards governing eligibility and the award of contracts to QIOs. We are proposing to replace nomenclature that has been amended by

the TAAEA, revise the existing definition in Part 475, Subpart A and Part 476, Subpart A of the term ''physician'', add new definitions to Part 475, Subpart A as necessary to support proposed new substantive provisions in Part 475, Subpart C, and revise, add, and replace some substantive provisions in Part 475, Subpart C.

1. Proposed Nomenclature Changes

In order to conform the regulations to the nomenclature changes made by section 261 of the TAAEA, we are proposing nomenclature changes where necessary in 42 CFR Part 475. We are, for example, proposing to revise the heading of Subpart C of Part 475 to read ''Subpart C—Quality Improvement Organizations'' and to replace the term ''peer review'' with ''quality improvement.'' In each proposed provision in Part 475, Subpart C, we use the new nomenclature where appropriate.

In addition, Part 476 is currently entitled ''Utilization and Quality Control Review,'' and Subpart C of Part 476 is entitled ''Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs),'' both of which reflect the terminology used before enactment of the TAAEA. In order to reflect the nomenclature changes made by the TAAEA, we are proposing to revise the title of Part 476 to read: ''Part 476—Quality Improvement Organization Review'' and the title of Subpart C of Part 476 to read: ''Subpart C—Review Responsibilities of Quality Improvement Organizations (QIOs).''

2. Proposals To Add and Revise Definitions

We are proposing changes to §§ 475.101 through 475.107 to reflect new eligibility standards for an entity to be awarded a QIO contract and to use specific terms that will be used to describe QIOs and their quality improvement work. In connection with these changes, we are proposing to add definitions of ''case review'', and ''QIO area,'' add cross-references to definitions in § 476.1 of ''practitioner'' and ''quality improvement initiative,'' and revise the definition of ''physician'' under § 475.1 and § 476.1, as discussed below. We are soliciting public comments on our proposed definitions.

We are proposing to define ''case reviews'' to mean ''the different types of reviews that QIOs are authorized to perform. Such reviews include, but are not limited to: (1) Beneficiary complaint reviews; (2) general quality of care reviews; (3) Emergency Medical Treatment and Labor Act (EMTALA) reviews; (4) medical necessity reviews, including appeals and DRG validation reviews; and (5) admission and discharge reviews.'' We are providing this list to illustrate the range and scope of case reviews but note that the Act and other provisions in Chapter IV of Title 42 of the Code of Federal Regulations require additional reviews and that the Secretary, pursuant to section 1154(a)(18) of the Act, may require additional reviews under the contracts awarded to QIOs.

We are proposing to expand the definition of ''physician'' beyond its existing definition under § 475.1 and § 476.1 to reflect the definition in section 1861(r) of the Act, as well as to cover several additional characteristics that are unique to the QIO Program. We are proposing the following definition of physician for both Parts 475 and 476: A physician is ''(1) A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor as described in section 1861(r) of the Act; (2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) above; and (3) An individual licensed to practice as a doctor as described in paragraph (1) above in any Territory or Commonwealth of the United States of America.'' We believe these revisions are necessary to eliminate references in paragraphs (1) and (2) of the definition in § 475.1 to physicians licensed in the State in which the QIO is located, in order to reflect the fact that a QIO's contract area may no longer be limited to one State. In addition, we are proposing to amend paragraph (3) of the definition in § 475.1 so that it no longer applies to just American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands. We are proposing to enlarge this part of the definition to apply to physicians licensed to practice in all U.S. Territories and Commonwealths to more closely align with the Secretary's flexibility in awarding QIO contracts granted by the TAAEA. We are soliciting public comments on whether our proposed definition is sufficiently inclusive and appropriate to achieve these goals. We also are proposing to define the term ''practitioner'' and ''quality improvement initiative'' for purposes of Part 475 by cross-referencing the existing definitions at 42 CFR 476.1.

In connection with our proposal to revise the requirements that an entity must meet to serve as a QIO, we also are proposing to define, in § 475.1, the terminology related to the geographic area in which a QIO must perform its different functions. Currently, the regulations in Part 475 do not define this area, but do refer to a QIO's ''review area'' in a number of places in existing text at §§ 475.102 and 475.103 and ''QIO area'' in §§ 475.1, 475.105(a), and 475.107(a) and (d). The term ''review area'' was used to refer to the geographic area in which each QIO performs its review functions under its contract with CMS while the term ''QIO area'' was used to refer to the geographic area covered by the contract. We are proposing to define and use the term ''QIO area'' to mean ''the defined geographic area, such as the State(s), region(s), or community(ties), in which the CMS contract directs the QIO to perform.'' Our addition of this proposed definition is meant to reflect the flexibility afforded to us by the TAAEA to establish a QIO area as the geographic area we believe will be most effective in accomplishing the goals of a particular QIO contract. In addition, the change in terminology from ''QIO review area'' to ''QIO area'' is intended to emphasize that the term can encompass more than just ''review'' functions. With this change, we intend to not only broaden the scope for choosing an appropriately sized geographic area, but also to identify capability and functionality as the primary way to identify the appropriate organization to perform specific QIO contract functions.

3. Proposals Relating To Scope and Applicability of Subpart C of Part 475

We believe that the scope and applicability provision for 42 CFR Part 475, Subpart C should reflect that the statutory authority for the QIO program was amended by the TAAEA, in particular the definition of a QIO and the eligibility and contracting standards. We are proposing to replace the regulatory language in § 475.100 with new language that explicitly acknowledges that the regulations in Subpart C implement sections 1152 and 1153(b) and (c) of the Act as amended by section 261 of the TAAEA. In addition, we are proposing to include the reference to section 1153(c) of the Act to reflect our proposal, in § 475.107(c), to include the 5-year contract term that now appears in amended section 1153(c)(3) of the Act. The proposed revisions to §§ 475.101 through 475.107 are intended to allow organizations that currently perform QIO work to compete for new QIO contracts, while expanding eligibility to additional entities under the new authority granted by the TAAEA. As the program evolves, we will focus contract determinations on the ability of

organizations to perform QIO functions as stated in the Request for Proposal (RPF). We are soliciting public comments on whether our proposed regulation text for Subpart C of Part 475 sufficiently meets this goal as well as our explained goal to implement the flexibility provided by Congress in the TAAEA amendments.

4. Proposals Relating to Eligibility Requirements for QIOs (§§ 475.101 through 475.106)

Prior to the TAAEA amendments, section 1152 of the Act defined a QIO as an entity that: (1) Is composed of a substantial number of licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area where the QIO will perform or has available the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the area where the QIO will perform to assure adequate review of the services provided by various medical specialties and subspecialties; (2) is able, in the judgment of the Secretary, to perform review functions in a manner consistent with the efficient and effective administration of the QIO statute and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and (3) has at least one individual who is a representative of consumers on its governing body. In section 261 of the TAAEA, Congress replaced the first two of these requirements with requirements that a QIO: (1) Be able, as determined by the Secretary, to perform QIO functions in a manner consistent with the efficient and effective administration of Part B of Title XI and Title XVIII of the Act; and (2) have at least one individual who is a representative of health care providers on its governing body. Congress left unchanged the third requirement in section 1152(3) of the Act that a QIO have at least one individual representing consumers on its governing body. We have interpreted and the regulations in Part 475 implement the statutory definition in section 1152 of the Act as setting minimum eligibility requirements for an entity to hold a QIO contract. Our regulatory proposal in this proposed rule would implement the changes in the QIO eligibility standards made by the TAAEA.

We recognize the vital role of physicians in the work of the QIOs and also believe that some of the functions of the QIOs necessitate a multidisciplinary approach to quality improvement, inclusive of expertise from a wide breadth of disciplines. With the elimination of the requirement that a QIO be sponsored by or have access to physicians in a specific organization structure, we are proposing to delete the eligibility requirements in §§ 475.101 through 476.104 related to the concepts of ''physician-sponsored organization'' and ''physician-access organization.'' In light of the current multidisciplinary approach to QIO activities, we believe that expanding the existing eligibility requirements beyond ''physician-sponsored organizations'' and ''physician-access organizations'' will both better reflect the flexibility Congress provided in the TAAEA amendments to section 1152 of the Act and be inclusive of the multidisciplinary approach that currently exists in contemporary quality improvement.

In addition, to implement the language added by section 261 that a QIO must be able, as determined by the Secretary, to perform the functions under the Act consistent with the purposes of the QIO program and the Medicare program, we are proposing language in §§ 475.101 through 475.103 to distinguish the requirements for QIOs to be able to perform case reviews from the requirements for QIOs to be able to perform quality improvement initiatives. We are soliciting public comments on our focus on these primary QIO functions and how this functional approach will ensure that QIOs are appropriately selected for contract award. We are proposing to vacate and reserve existing §§ 475.104 and 475.106.

a. Eligibility To Be Awarded a QIO Contract (§ 475.101)

As proposed here, revised § 475.101 would no longer reference ''physician-sponsored organizations'' and ''physician-access organizations,'' would retain the requirement that the governing body of the QIO include at least one consumer representative, and would include new eligibility standards for an organization to be awarded a QIO contract based on the TAAEA amendments to section 1152 of the Act. First, in paragraph (a), we are proposing that a QIO must have a governing body that includes at least one representative of health care providers and one representative of consumers as required by section 1152(2) and (3) of the Act as amended by the TAAEA. Second, in paragraph (b), we are proposing to interpret and implement the amended language in section 1152(1) of the Act that an organization awarded a QIO contract must be able, as determined by the Secretary, to perform the functions under the Act consistent with the purposes of the QIO program and the Medicare program by requiring that an organization demonstrate the ability to meet eligibility requirements and perform the functions of a QIO. Our proposal characterizes the functions of a QIO as the contractual requirements for QIOs to perform activities that are built into the request for proposals used to award QIO contracts and the ability to perform case reviews and/or quality improvement initiatives as described in these regulations. In our view, these broad categories encompass the work QIOs are required to perform under section 1154 of the Act. Our proposal reflects a different approach to structuring the QIO requirements than the current rule; we are proposing to focus on the functions the organization performs under the QIO contract instead of the structure of the organization itself. As discussed in more detail below in connection with proposed §§ 475.102 and 475.103, this function-focused approach also reflects both the important role of physicians and a multidisciplinary approach for the two primary functions of the QIO contracts: (1) Case reviews and (2) quality improvement initiatives. These two primary functions are based on the statutory requirements for the functions QIOs must perform and our current approach of using quality improvement initiatives to improve the quality of care provided to Medicare beneficiaries. By referencing the contractual requirements set forth in the requests for proposals, we are proposing to incorporate the flexibility provided in section 1154(a) to require a QIO to perform one or more of the listed QIO functions and section 1154(a)(18) of the Act for the inclusion of additional activities for QIOs to perform when we determine that they are necessary to improve the quality of care for Medicare beneficiaries.

Finally, in paragraph (c), we are proposing that a QIO must demonstration the ability to actively engage beneficiaries, families, and consumers, as applicable, in case reviews and quality improvement initiatives. Although this is not a specifically required qualification for a QIO under sections 1152 and 1153 of the Act, we are proposing this requirement because it reflects the multidisciplinary and multistakeholder approach to QIO functions that we intend to establish. Health care costs have doubled as a share of the economy over the past three decades, causing stress on beneficiaries, families, employers, and government budgets. We believe that motivating beneficiaries to

become involved in their own health care may reduce waste and ultimately improve the quality and efficiency of health care. One important way to accomplish this is by educating beneficiaries, their families, providers, and the public about the importance of identifying and pursuing value in health care. Value represents the best possible quality of health care at the most reasonable cost. A major component of a successful value initiative depends on a QIO's understanding of patient and family goals, expectations, motivations, and aspirations. Our inclusion of the requirement that a QIO have the ability to understand the needs of beneficiaries, families, and consumers and actively engage them in health care decisions emphasizes our commitment to patient and family engagement as an essential component of the QIO program.

We are soliciting public comments on whether our proposal sufficiently incorporates the statutory flexibility, identifies the goals of the QIO eligibility requirements, and provides guidance on how organizations will be determined eligible for QIO contracts.

b. Eligibility Requirements for QIOs to Perform Case Reviews (§ 475.102)

In this proposed rule, we are proposing to list the *type* of factors CMS will use to determine that an organization has demonstrated its ability to perform case reviews. We do not consider this list to be comprehensive, but an indication of what we intend to focus on. The list of factors emphasizes the importance of QIOs having access to qualified physicians and practitioners for this purpose. In paragraph (a) of § 475.102, we are proposing that CMS will determine that an organization has demonstrated the ability to perform case reviews based on factors related to how the QIO work will be performed and the underlying capabilities necessary for performing well. Under our proposal, CMS will consider such factors as (1) the organization's proposed processes, capabilities, quantitative and/or qualitative performance objectives, and case review methodology; (2) the organization's proposed involvement of and access to physicians and practitioners in the QIO area with appropriate expertise and specialization in the areas of health care related to case reviews; (3) the organization's ability to take into consideration urban versus rural and regional characteristics in the health care setting where the care under review was provided; (4) the organization's ability to take into consideration evidence-based national clinical guidelines and professionally recognized standards of care; and (5) the organization's access to qualified information technology (IT) expertise. In this paragraph, we intend to propose these general factors and standards CMS may use to establish the minimum level of resources and skills the organization must have in order to demonstrate that its processes and capabilities are satisfactory and meet the purposes of the QIO program.

In paragraph (b) of § 475.102, we are proposing that CMS may consider characteristics such as the geographic location, size and prior experience of an organization in order to determine whether the organization has the capability to perform case reviews. In terms of prior experience, we are proposing that CMS will gauge the significance of an organization's experience based on how relevant it is to the tasks that CMS intends to include in the QIO contract and the goals CMS intends to accomplish. While we intend to emphasize the importance of prior experience, we do not intend to limit the evidence an organization may present to us to demonstrate its capability to perform case reviews. Therefore, we have included language in proposed § 475.102(b) to indicate that CMS can consider a variety of factors, as indicated in section 1153(b)(4) of the Act.

Finally, we are proposing to include in paragraph (c) of § 475.102 clarifications to the text that reflect the existing regulatory text at § 475.104(d), with some minor modifications. The existing provision states that a State government that operates a Medicaid program will be considered incapable of performing utilization and quality review functions in an effective manner, unless the State demonstrates to CMS' satisfaction that it will act with complete independence and objectivity. As proposed, the provision at § 475.102(c) maintains the substance of the existing rule while making it clear that the scope of its review will be limited to case reviews. In order to do this, we have proposed to replace the term ''utilization and quality review functions'' with the term ''case reviews.'' In addition, we are proposing to revise the language to clarify that the objectivity and independence mentioned in the existing regulation relate to objectivity and independence from the Medicaid program, as we believe there is an inherent conflict of interest that arises from the State's financial interest in the administration of that program.

Our proposal at § 475.102 implements the statutory responsibility for the Secretary to determine whether an organization can perform the QIO function of case reviews in a manner that is consistent with the efficient and effective operation of the QIO Program and the Medicare Program. We are soliciting public comments on whether the regulation text should incorporate the standards for QIOs that we propose to use and the factors we intend to consider when determining whether those standards have been met.

We are proposing to delete and reserve all of § 475.104 in light of our proposed changes to § 475.102. We believe that aspects of § 475.104 that we have not proposed to incorporate into § 475.102 are obsolete due to the revisions in the TAAEA legislation.

c. Eligibility Requirements for QIOs to Conduct Quality Improvement Initiatives (§ 475.103)

Case reviews are concerned with care that was provided, or should be provided, based on the facts of a particular case, concerning a particular episode of care or concerning a particular beneficiary, or both. By contrast, the vast majority of quality improvement initiatives are not initiated in the same manner as case reviews. Rather, quality improvement initiatives are based on patterns of care that reveal problems that are more systematic in nature, such as those that result in inefficiency, waste, or high cost, or that could potentially harm beneficiaries. These patterns of care can reflect problems that might impact large segments of the population, or single episodes of care where the impact might affect fewer people, but the QIO is concerned about the health and safety of the public due to the severity of the quality of care issue. We are proposing under revised § 475.103(a) that CMS will determine if an organization is capable of performing quality improvement initiatives using factors similar to those listed for QIOs that will perform case reviews. In paragraph (a), we are proposing a list of the type of factors CMS will use to determine that an organization has demonstrated its ability to perform quality improvement initiatives. We do not consider this list to be comprehensive, but an indication of what we intend to focus on. Specifically, in revised paragraph § 475.103(a), we are proposing that CMS will determine that an organization has demonstrated the ability to perform quality improvement initiatives based on factors tied to how the QIO work will be performed and the underlying capabilities necessary for performing well. Under our proposal, CMS will consider such factors as (1) The organization's proposed processes,

capabilities, quantitative and/or qualitative performance objectives, and methodology to perform quality improvement initiatives; (2) the organization's proposed involvement of and access to physicians and practitioners in the QIO area with appropriate expertise and specialization in the areas of health care concerning the quality improvement initiative; and (3) the organization's access to professionals with requisite knowledge of quality improvement methodologies and practices as well as qualified information technology and technical expertise. We plan to use these factors, and others as necessary, to determine if an organization has satisfactory capabilities and sufficient resources to initiate, follow up on, and follow through to completion quality improvement initiatives that it agrees to undertake. We consider appropriate quality improvement resources to include a multidisciplinary team that is comprised of appropriate health care professionals to perform quality improvement initiatives as well as the administrative, IT and technical staff necessary to accomplish the quality improvement initiatives.

In paragraph (b), we are proposing that CMS may consider characteristics such as the geographic location, size, and prior experience of an organization in order to determine whether the organization has the capability to perform quality improvement initiatives. In terms of prior experience, we are proposing that CMS will gauge the significance of an organization's experience based on how relevant it is to the tasks that CMS intends to include in the QIO contract and the goals CMS intends to accomplish. While we intend to emphasize the importance of prior experience, we do not intend to limit the evidence an organization may present to us to demonstrate its capability to perform quality improvement initiatives. We are proposing to include language in proposed § 475.103(b) to indicate that CMS can also consider a variety of other factors, as indicated in section 1153(b)(4) of the Act.

Finally, we are proposing to include in paragraph (c) clarifications to the text that reflect the existing regulatory text at § 475.104(d), with some minor modifications. The current provision states that a State government that operates a Medicaid program will be considered incapable of performing utilization and quality review functions in an effective manner, unless the State demonstrates to CMS' satisfaction that it will act with complete independence and objectivity. As proposed, the provision at § 475.103(c) maintains the substance of the existing rule while making it clear that the scope of its review will be limited to quality improvement initiatives. In order to do this, we have proposed to replace the term ''utilization and quality review functions'' with the term ''quality improvement initiatives.'' In addition, we are proposing to revise the language to clarify that the objectivity and independence mentioned in the existing regulation relate to objectivity and independence from the Medicaid program, as we believe there is an inherent conflict of interest that arises from the State's financial interest in the administration of that program.

Our proposal at § 475.103 implements the statutory responsibility for the Secretary to determine whether an organization can perform the QIO function of quality improvement initiatives in a manner that is consistent with the efficient and effective operation of the QIO Program and the Medicare Program. We solicit comment on whether the regulation text should incorporate the standards for QIOs that we propose to use and the factors we intend to consider when determining whether those standards have been met.

d. Prohibitions on Eligibility as a QIO (§ 475.105)

We are proposing revisions to § 475.105(a)(2) to eliminate the prohibition against an association of health care facilities being awarded a QIO contract, to reflect a TAAEA amendment deleting this restriction from section 1153(b)(3) of the Act. We also are proposing to move the existing provision covering the exclusion of health care facility affiliates in paragraph (a)(3) to paragraph (a)(2), and to create a revised paragraph (a)(3) that would include payor organizations as excluded entities unless they meet certain exception requirements identified in section 1153(b)(2)(B) of the Act. Prior to the TAAEA amendment, the statute imposed two prohibitions on CMS contracting with a payor organization to perform QIO functions: A prohibition applicable before November 15, 1984 and a prohibition with exceptions for periods of time after November 15, 1984. After November 15, 1984, a payor organization could perform as a QIO if the Secretary determined that there were no other entities available for a QIO area. These restrictions were implemented in the existing regulations codified at §§ 475.105(b) and 475.106. The TAAEA amendments left unchanged the prohibition in effect for the period of time before November 15, 1984, but revised section 1153(b)(2)(B) of the Act to add exceptions to the prohibition applicable after November 15, 1984. Section 1153(b)(2)(B) of the Act, as amended, permits the award of a QIO contract to a payor organizations not only when the Secretary determines that there is no other entity available for an area, but also when the Secretary determines that there is a more qualified entity to perform one or more of the functions in section 1154(a) of the Act, if the entity meets all other requirements and standards in the QIO statute. We read this provision to mean that when the Secretary determines that a payor organization is more qualified than a nonpayor organization in the QIO area to perform one or more of the functions in section 1154(a) of the Act, that payor entity can qualify as a QIO so long as all other eligibility criteria are met. We have reflected this interpretation in the proposed rule as § 475.105(a)(3).

The existing paragraph (b) prohibits payor organizations from being QIOs prior to November 15, 1984. Since that date has long passed, we believe this paragraph should be eliminated. We are proposing to delete and reserve paragraph (b) of § 475.105 in its entirety. Paragraph (c) would remain largely unchanged except for a minor terminology update to clarify in the regulation text that the term ''facility'' is meant to refer to a ''health care facility'' and to change the term ''conduct any review activities'' to ''perform any case review activities'' to indicate our separation of case review functions from quality improvement initiatives. We do not believe that these changes affect the underlying prohibitions.

As noted above, we are proposing to delete and reserve all of § 475.106 in light of our proposed changes to § 475.105. We believe that aspects of § 475.106 that we have not proposed to incorporate into § 475.105 are obsolete due to the passage of time.

5. Proposals Relating to QIO Contract Awards (§ 475.107)

The existing regulations at 42 CFR Part 475 also include requirements related to the establishment of QIO contracts and the assignment of bonus points. We are proposing to delete the portions of existing § 475.107(c) pertaining to the assignment of up to 10 percent of available bonus points to physician-sponsored organizations, and the assignment of points in connection with the structure of the organization as ''physician-sponsored'' or ''physician-access.'' These provisions are obsolete in light of the changes to section 1152(1) of the Act and our proposals above

relating to the eligibility standards for an organization awarded a QIO contract. We also are proposing to use cross-references in § 475.107(a) and (b) to the revised standards we are proposing in §§ 475.101 through 475.103. We are proposing to retain the regulatory language that requires CMS to identify proposals that meet the requirements of § 475.101 (proposed § 475.107(a)) and to identify those proposals that set forth minimally acceptable plans in accordance with the requirements of § 475.102 or § 475.103, or both as applicable (proposed § 475.107(b)).

The existing § 475.107(d) states that the contract for a given QIO area to the selected organization cannot exceed 2 years, which is inconsistent with the current statutory provision at section 1153(c)(3) of the Act. We are proposing here to redesignate this provision as paragraph (c) and to provide for a 5-year contract term as required by section 1153(c)(3) of the Act, as amended by section 261 of the TAAEA.

XVIII. Medicare Fee-for-Service Electronic Health Record (EHR) Incentive Program

A. Incentive Payments for Eligible Professionals (EPs) Reassigning Benefits to Method II CAHs

Section 1848(o)(1)(A) of the Act, as amended by section 4101(a) of the HITECH Act, establishes the Medicare EHR Incentive Program, which provides for incentive payments to eligible professionals (EPs) who are meaningful users of certified EHR technology during the relevant EHR reporting periods. Section 1848(o)(1)(A)(i) of the Act provides that EPs who are meaningful EHR users during the relevant EHR reporting period are entitled to an incentive payment amount, subject to an annual limit, equal to 75 percent of the Secretary's estimate of the Medicare allowed charges for covered professional services furnished by the EP during the relevant payment year. Under section 1848(o)(1)(B)(ii) of the Act, an EP is entitled to an incentive payment for up to 5 years. In addition, in accordance with section 1848(o)(1)(A)(ii) of the Act, there shall be no incentive payments made with respect to a year after 2016.

1. Background for Definition of EPs and EHR Incentive Payments to EPs

In accordance with section 1848(o)(5)(C) of the Act, in the final rule for Stage 1 of the EHR Incentive Program (75 FR 44442), we established a definition of the term ''eligible professional'' in the regulations at 42 CFR 495.100 to mean a physician as defined under section 1861(r) of the Act. Section 1861(r) of the Act defines the term ''physician'' to mean the following five types of professionals, each of which must be legally authorized to practice their profession under State law: A doctor of medicine or osteopathy; a doctor of dental surgery or dental medicine; a doctor of podiatric medicine; a doctor of optometry; or a chiropractor. As also discussed in that final rule (75 FR 44439), in accordance with section 1848(o)(1)(C) of the Act, hospital-based EPs are not eligible for an EHR incentive payment. The term ''hospital-based EP'' is defined in § 495.4 of the regulations as ''Unless it meets the requirements of § 495.5 of this part, a hospital-based EP means an EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the payment year, or in the case of a payment adjustment year, in either of the 2 years before such payment adjustment year.'' Paragraphs (1)(i) and (1)(ii) of the definition specify how the percentage of covered professional services is calculated for Medicare for purposes of the payment years and payment adjustment years, respectively. We note a discrepancy between the regulation text for this definition and the final policy we established in the preamble of the EHR Incentive Program Stage 2 final rule (77 FR 54102). Under the policy we finalized in that rule, we determine whether an EP is hospital-based for a payment adjustment year using either of the following Federal fiscal year's (FY) data: (1) The fiscal year before the year that is 1 year prior to the payment adjustment year (for example, FY 2013 data for payment adjustment year 2015); or (2) the fiscal year before the year that is 2 years prior to the payment adjustment year (for example, FY 2012 data for payment adjustment year 2015). If the data from either year result in a hospital-based determination, the EP would not be subject to the payment adjustments for the relevant year. In the definition under § 495.4 of the regulations, however, paragraph (1)(ii) incorrectly refers to the fiscal year preceding the payment adjustment year and the fiscal year 2 years before the payment adjustment year. The introductory text of the definition also incorrectly references either of the 2 years before such payment adjustment year. We are taking this opportunity to make a technical correction to paragraph (1)(ii) and the introductory text of the definition of ''hospital-based EP'' at § 495.4 to conform to the policy stated in the preamble of the EHR Incentive Program Stage 2 final rule (77 FR 54102). We are proposing to revise paragraph (1)(ii)(A) of the definition to read ''The Federal fiscal year 2 years before the payment adjustment year; or'' and paragraph (1)(ii)(B) of the definition to read ''The Federal fiscal year 3 years before the payment adjustment year.'' We also are proposing to revise the introductory text of the definition to reference, in the case of a payment adjustment year, either of the 2 years before the year preceding such payment adjustment year. Section 1848(o)(5)(A) of the Act defines covered professional services as having the same meaning as in section 1848(k)(3) of the Act; that is, services furnished by an eligible professional for which payment is made under, or is based on, the Medicare Physician Fee Schedule (MPFS). In accordance with section 1848(a)(1) of the Act, the Medicare allowed charge for covered professional services is the lesser of the actual charge or the MPFS amount established in section 1848 the Act. As specified under section 1848(o)(1)(A)(i) of the Act, the Secretary's estimate of allowed charges for EHR incentive payments is based on claims submitted to Medicare no later than 2 months following the end of the relevant payment year.

Section 1848(o)(1)(B)(i) of the Act sets forth the annual limits on the EHR incentive payments to EPs. Specifically, section 1848(o)(1)(B) of the Act provides that the incentive payment for an EP for a given payment year shall not exceed the following amounts:

- For the EP's first payment year, for such professional, $15,000 (or $18,000, if the EP's first payment year is 2011 or 2012);
- For the EP's second payment year, $12,000;
- For the EP's third payment year, $8,000;
- For the EP's fourth payment year, $4,000;
- For the EP's fifth payment year, $2,000; and
- For any succeeding year, $0.

Under section 1848(o)(1)(B)(iv) of the Act, for EPs who predominantly furnish services in a geographic HPSA (as designated by the Secretary under section 332(a)(1)(A) of the Public Health Service Act), the incentive payment limitation amounts for each payment year are increased by 10 percent. Section 1848(o)(1)(B)(iii) of the Act also provides for a phased reduction in payment limits for EPs who first demonstrate meaningful use of certified EHR technology after 2013. Section 1848(o)(1)(D)(i) of the Act, as amended

by section 4101(a) of the HITECH Act, provides that the incentive payments may be disbursed as a single consolidated payment or in periodic installments as the Secretary may specify. We make a single, consolidated, annual incentive payment to EPs. Payments are made on a rolling basis, as soon as we ascertain that an EP has demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year or a calendar year for subsequent years), and reached the threshold for maximum payment.

Section 1848(o)(1)(A) of the Act provides that ''with respect to covered professional services provided by an eligible professional,'' the incentive payment ''shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)).'' Section 1842(b)(6)(A) of the Act allows for reassignment of payments to an employer or entity with which the physician has a valid contractual arrangement allowing the entity to bill for the physician's services. Therefore, we provided that EPs would be allowed to reassign their incentive payments to their employer or an entity that they have a valid employment agreement or contract providing for such reassignment, consistent with all rules governing reassignments (75 FR 44445). Section 495.10(f) of the regulations permits EPs to reassign their incentive payments to an employer or to an entity with which they have a contractual arrangement, consistent with all rules governing reassignments, including 42 CFR Part 424, Subpart F. Section 495.10(f) also precludes an EP from reassigning the incentive payment to more than one employer or entity. To implement this requirement, we use the EP's Medicare enrollment information to determine whether an EP belongs to more than one practice (that is, whether the EP's National Provider Identifier (NPI) is associated with more than one practice). In cases where an EP is associated with more than one practice, the EP would select one tax identification number to receive any applicable EHR incentive payment.

2. Special Circumstances of EPs Reassigning Benefits to Method II CAHs

Since we implemented the EHR Incentive Program, we have received many requests from CAHs billing under Method II (Method II CAHs), members of Congress, and hospital associations requesting that we make it possible for EPs who assign their reimbursement and billing to a Method II CAH to participate in the program. Under section 1834(g)(2) of the Act, a CAH may elect to receive a cost-based payment for the facility costs of providing outpatient services, plus 115 percent of the fee schedule amount for professional services included within outpatient CAH services. CAHs that elect to receive both a facility payment and a professional payment for outpatient services are commonly referred to as Method II CAHs. The statute also provides that, as a condition for applying this provision, the Secretary may not require that each physician or other practitioner providing professional services in a CAH must assign billing rights for such services to the CAH. Physicians and other practitioners who do not assign such rights to their Method II CAH continue to receive payment for their professional services directly under the appropriate professional fee schedule.

Since the inception of the EHR Incentive Program, we have been unable to account for the services furnished by EPs in Method II CAH outpatient departments (including emergency departments) due to limitations in our information systems. Specifically, our information systems have not been capable of receiving and storing line-level rendering EP identifying information for these Method II CAH claims for services furnished by EPs in outpatient departments. These claims are billed by the CAH on behalf of the EPs furnishing the services using the institutional claim form UB–04 or its electronic counterpart, the X12 837I format. Until a recent information systems change was implemented, we were unable to identify the NPI of the EP furnishing the service at the service line-level on the claim. While the information systems received and stored NPIs from each claim, the NPIs were not tied to the specific services furnished on the claim. This limitation made it impossible to take into account the services furnished by EPs in Method II CAH outpatient settings when we annually determined the hospital-based status of each EP for each payment year for purposes of the EHR Incentive Program. In addition, for those EPs who were determined to be not hospital-based and who successfully demonstrated meaningful use, we were unable to take into account such services in calculating the amount of an EP's EHR incentive payment for a payment year. Because the limitations in our information systems prevented us from identifying the NPIs of the EPs who furnished the services on the Method II CAH claims, we were unable to include those claims for purposes of the hospital-based determinations and EHR incentive payment calculations. However, it is important to note that these EPs could still participate in the EHR Incentive Program and qualify for an incentive payment based on their non-Method II CAH claims.

We began soon after the implementation of the EHR Incentive Program to develop the requisite changes so that our information systems would be able to receive and store line-level rendering EP identifying information for these Method II CAH claims. We were able to implement these information systems changes effective for claims submitted on or after October 1, 2012 (in other words, on or after the start of FY 2013). Under the existing regulations at § 495.4, we determine an EP's hospital-based status for a payment year based on claims data from the fiscal year preceding the payment year. Thus, for purposes of the 2013 payment year, we determine whether an EP is hospital-based using claims data from FY 2012. However, as noted above, we are unable to take into account Method II CAH claims prior to the start of FY 2013. As a result, under the existing regulations, the hospital-based determinations for EPs for the 2013 payment year are based on FY 2012 claims data that do not include Method II CAH claims. The earliest that we would be able to include such claims under the existing regulations would be for the hospital-based determinations for the 2014 payment year, which are based on FY 2013 claims data.

We want to avoid further delay in taking into account the services furnished by EPs in Method II CAH outpatient settings. Therefore, we are proposing to add a provision to the definition of ''hospital-based EP'' at § 495.4 under new paragraph (3) to provide a special methodology for making hospital-based determinations for the 2013 payment year for EPs with services billed by Method II CAHs. We are making this proposal solely in order to take into account the special circumstances of those EPs as described above. Under this proposal, we would be able to take into account Method II CAH claims when making hospital-based determinations for payment year 2013, one year before we would be able to do so under the existing regulations. Specifically, we are proposing that, for payment year 2013 only, we would use a two-step process to make hospital-based determinations for EPs who furnish covered professional services billed by Method II CAHs. First, after we have accumulated the Method II CAH claims with the line-level furnishing EP identifying information for FY 2013

(October 1, 2012 through September 30, 2013), we would use that data to identify which EPs had Method II CAH service billings during that year, and we would make a special hospital-based determination for that subset of EPs for payment year 2013. Any EP determined to be nonhospital-based on the basis of FY 2013 claims data would be eligible to demonstrate meaningful use for the relevant EHR reporting period and potentially qualify for an EHR incentive payment for payment year 2013. An EP who believes that he or she would be determined to be nonhospital-based under this proposed provision and wishes to qualify for the EHR incentive payment for payment year 2013 should not wait for the determination to implement Certified EHR Technology and begin meaningful use for an EHR reporting period in 2013. To qualify for an EHR incentive payment for payment year 2013, an EP will need to demonstrate meaningful use of Certified EHR Technology for an EHR reporting period in 2013. As is the case with other EPs that reassign their EHR incentive payments to another entity, these EPs may reassign their EHR incentive payments to the Method II CAH that bills on their behalf if the CAH is an employer or they have a contractual arrangement, consistent with the rules governing reassignments. Second, in the case of an EP determined to be hospital-based on the basis of FY 2013 claims data, we would check the hospital-based determination we have already for that EP under the existing regulation using the FY 2012 file. Any EP found to be nonhospital-based on the basis of the FY 2012 claims data (which do not include Method II CAH claims) would be held harmless to the determination made on the basis of FY 2013 claims data and considered nonhospital-based for payment year 2013. We believe that this second step of the proposed methodology is important to protect EPs who were initially determined nonhospital-based at the beginning of payment year 2013 under the existing regulation. We do not believe those EPs who were determined nonhospital-based under the existing regulation should have those determinations reversed by later (although more complete) FY 2013 claims data. This hold-harmless provision would preserve the prospectivity of nonhospital-based determinations for payment year 2013 that were made under the existing regulation and maintain the eligibility of those EPs to receive EHR incentive payments for payment year 2013. At the same time, the first step of our proposal would provide an opportunity for EPs who were determined to be hospital-based for payment year 2013 on the basis of FY 2012 data, which did not include the Method II CAH claims for their services, to establish their nonhospital-based status on the basis of the more complete FY 2013 data. It is important to note that, due to the systems limitations described above, we are unable to propose any special method for making EHR incentive payments and hospital-based determinations for the payment years prior to payment year 2013. We lack the ability to retrieve line-level furnishing EP identifying information for Method II CAH claims during the years prior to FY 2013. We are inviting public comments on this proposal.

B. Cost Reporting Periods for Interim and Final EHR Incentive Payments to Eligible Hospitals

1. Background

In the July 28, 2010 final rule for Stage 1 of the EHR Incentive Program, we established the cost report periods from which we would draw the requisite data (for example, hospital acute care inpatient discharges and Medicare Part A acute care inpatient days) for determining interim and final EHR incentive payments to eligible hospitals (75 FR 44450). We specified in § 495.104(c)(2) of the regulations that we would use discharge and other relevant data from the hospital's most recently submitted 12-month cost report in order to determine preliminary hospital EHR incentive payments. Similarly, we specified in § 495.104(c)(2) that we would make final EHR incentive payments to hospitals based on discharge and other relevant data from the hospital's first 12-month cost reporting period that begins on or after the first day of the payment year. (For purposes of EHR incentive payments for eligible hospitals, a payment year is a Federal fiscal year.) As we noted in the final rule (75 FR 44450 through 44451), section 1886(n)(2)(C) of the Act requires that a ''12-month period selected by the Secretary'' be employed for purposes of determining the discharge related amount. As we also stated in that final rule (77 FR 44452), we believe that the requirement for using 12-month cost reporting periods for purposes of determining preliminary and final payments is important to avoid the use of nonstandard cost reporting periods, which are often quite short (for example, 3 months) and therefore are ''not likely to be truly representative of a hospital's experience, even if methods were to be adopted for extrapolating data over a full cost reporting period.''

2. Special Circumstances

Since the publication of the EHR Incentive Program final rule for Stage 1, we have become aware of circumstances in which the only cost reporting period for an eligible hospital that begins on or after the first day of a payment year is a nonstandard cost reporting period. For example, a hospital may be merging with another hospital under an arrangement in which its CCN, and therefore its existence as an identifiable hospital for Medicare EHR Incentive Program purposes, will not survive the merger. In such circumstances, the last cost reporting period for the hospital after its final payment year and prior to its merger into the surviving hospital may be a short period. In order to accommodate these situations, we are proposing to revise § 495.104(c)(2) of the regulations to provide that, in cases where there is no 12-month cost reporting period that begins on or after the beginning of a payment year, we will use the most recent 12-month cost reporting period available at the time of final settlement in order to determine final EHR incentive payments for the hospital. We understand that, under this proposal, the last available cost reporting period that we would use for the final determination of EHR incentive payments may be the same 12-month cost reporting period that had been used for purposes of determining the hospital's interim EHR incentive payments. We believe that this result is preferable to resorting to a nonstandard cost reporting period because a 12-month period is required by the statute to determine the discharge related amount and such periods tend, for reasons discussed in the EHR Incentive Program Stage 1 final rule, to be unrepresentative of the hospital's experience. We are inviting public comments on this proposal.

XIX. Medicare Program: Provider Reimbursement Determinations and Appeals

A. Matters Not Subject to Administrative or Judicial Review (§ 405.1804)

1. Background

Section 1878(a) of the Act addresses appeals of certain Medicare payment determinations to the Provider Reimbursement Review Board (the ''Board''). Below we briefly discuss the prospective payment system (PPS) under which payments for certain Medicare inpatient hospital services are made.

The Social Security Amendments of 1983 (Pub. L. 98–21) added section

1886(d) to the Act, which changed the method of payment for inpatient hospital services under Medicare Part A for short-term acute care hospitals. The method of payment for these hospitals was changed from a cost-based retrospective reimbursement system to a system based on prospectively set payment rates; that is, a PPS. Under Medicare's hospital inpatient prospective payment system (the hospital IPPS), payment is made at a predetermined rate for each hospital discharge.

The Social Security Amendments of 1983 also added section 1886(e)(1) to the Act, which required that, for cost reporting periods beginning in FYs 1984 and 1985, the IPPS result in aggregate program reimbursement equal to ''what would have been payable'' under the reasonable cost-based reimbursement provisions of prior law; that was, for FYs 1984 and 1985, the IPPS would be ''budget neutral.'' Section 1886(e)(1)(A) of the Act required that the projected aggregate payments for the hospital-specific portion should equal the comparable share of estimated reimbursement under prior law. Section 1886(e)(1)(B) of the Act required that projected aggregate reimbursement for the Federal portion of the prospective payment rates equal the corresponding share of estimated amounts payable prior to the passage of Public Law 98–21. In the 1983 IPPS interim final rule published in the **Federal Register** on September 1, 1983, we explained how the adjustment of the Federal portion of the prospective payment rate was determined, as well as the resulting adjustment factors for FY 1984 (48 FR 39887).

Under section 1878 of the Act and the regulations at Subpart R of 42 CFR Part 405, the Board has the authority to adjudicate certain reimbursement appeals by providers. The Board's decisions are subject to review by the Administrator of CMS under section 1878(f)(1) of the Act, as implemented by § 405.1875 of the regulations. A final decision of the Board, or any reversal, affirmance, or modification of a final Board decision by the Administrator, may be subject to review by a United States District Court.

2. Proposed Technical Conforming Change

Certain matters affecting payment to hospitals under the IPPS are not subject to administrative or judicial review. For example, section 1886(d)(7) of the Act precludes administrative and judicial review of the budget neutrality adjustment effected pursuant to section 1886(e)(1) of the Act. This preclusion of review is also reflected in section 1878(g)(2) of the Act (which states that ''determinations and other decisions described in section 1886(d)(7) shall not be reviewed by the Board or any other court . . . .''). The existing regulatory text at § 405.1804(a) provides that there is no administrative or judicial review of ''any budget neutrality adjustment in the prospective payment rates.''

The language of § 405.1804(a) was promulgated as part of the implementing regulations (48 FR 39785 and 39835) for the hospital IPPS. Section 405.1804(a) was codified pursuant to section 1886(d)(7) of the Act. At the time of promulgation, section 1886(d)(7) of the Act specified only the budget neutrality adjustment in section 1886(e)(1) of the Act. Additional budget neutrality adjustments under the IPPS were added by law and were not precluded from administrative or judicial review. For example, section 4410 of the Balanced Budget Act of 1997 (the BBA), Public Law 105–33, established the rural floor wage index budget neutrality adjustment, and did not preclude administrative or judicial review in the statute for this adjustment.

We recognize that the language of the regulation at § 405.1804(a) is overly broad because it states that there is no administrative or judicial review of ''any'' budget neutrality adjustment in the prospective payment rates, and its terms are not limited to the budget neutrality adjustment specified in section 1886(e)(1) of the Act. We understand that the Board has relied on § 405.1804(a) to deny jurisdiction in appeals relating to budget neutrality adjustments other than the adjustment in section 1886(e)(1) of the Act. To the extent that the existing § 405.1804(a) refers to ''any'' budget neutrality adjustment, we believe that this regulatory text is not consistent with the current statute. Therefore, we are proposing to make a technical conforming change to § 405.1804(a) to conform the regulation to the current statute. This proposed technical conforming change would clarify that there is no administrative or judicial review with respect to the budget neutrality adjustments enumerated in section 1886(e)(1) of the Act, and this preclusion of review does not apply to other budget neutrality adjustments under the IPPS.

B. Clarification of Reopening of Predicate Facts in Intermediary Determinations of Provider Reimbursement (§ 405.1885)

A provider must submit an annual cost report to a fiscal intermediary (currently referred to as a Medicare Administrative Contractor (MAC)), as specified in regulations at §§ 413.20(b) and 413.24(f). Through its review and settlement process, the intermediary determines the total amount of reimbursement due a provider for its cost reporting period. This constitutes an ''intermediary determination,'' as defined in § 405.1801(a). In accordance with § 405.1803, an intermediary determination is set forth in a notice of program reimbursement (NPR), which explains the intermediary's final determination of the total amount of program reimbursement due the provider for the cost reporting period in question.

Section 405.1803(b) requires that the NPR explain any differences between the intermediary determination and the amount of program reimbursement claimed by the provider. Such differences may be attributable to specific provisions of the Medicare statute, regulations, CMS rulings, or program instructions. In addition, the intermediary determination may reflect specific findings of fact by the intermediary that differ from the provider's understanding of the facts.

The factual underpinnings of a specific determination of the amount of reimbursement due a provider sometimes first arise in, or are determined for, the same fiscal period as the cost reporting period under review. For example, the determination of whether a hospital subject to the inpatient prospective payment system (IPPS) should receive a payment adjustment for serving a significantly disproportionate share of low income patients under section 1886(d)(5)(F) of the Act and § 412.106 of the regulations in a given fiscal period depends on the number of the hospital's patient days for the same period.

However, the factual underpinnings of a specific determination of the amount of reimbursement due a provider may first arise in, or be determined for, a different fiscal period than the cost reporting period under review. We refer to these factual determinations as ''predicate facts.'' For example, the determination of an IPPS-exempt hospital's target amount (that is, per-discharge (case) limitation) or rate-of-increase ceiling under section 1886(b) of the Act and regulations at § 413.40 depends on: (1) The hospital's allowable net inpatient operating costs for a base period of at least 12 months before the first cost reporting period subject to the rate-of-increase ceiling; or (2) for later cost reporting periods, the target amount for the preceding 12-month cost reporting period. The hospital's allowable costs for its base period are

''predicate facts'' with respect to the first cost reporting period that is subject to the target amount because such base period costs figure in the determination of the hospital's first target amount. The target amount for each cost reporting period after the base period then becomes a ''predicate fact'' for the next cost reporting period. We refer readers to section 1886(b)(3)(A) of the Act (for the first period, the target amount is calculated using ''allowable operating costs of inpatient hospital services for the preceding 12-month cost reporting period;'' the target amount for later cost reporting periods is calculated using the target amount for the preceding 12-month cost reporting period, increased by an applicable update factor).

A provider may challenge an intermediary determination by filing an appeal within 180 days of the NPR to the Board (under section 1878(a) of the Act and regulations at § 405.1835) or, if the amount in controversy is at least $1,000 but less than $10,000, to the intermediary hearing officer(s) (under § 405.1811). Alternatively, in accordance with § 405.1885, the provider may request that the intermediary reopen its NPR. In addition, the intermediary may reopen the NPR on its own motion. Under § 405.1885(b), reopening must be requested by the provider, or initiated on the intermediary's own motion, within 3 years of the NPR, although there is no time limit for the reopening of an intermediary determination that was procured by fraud or similar fault of a party to such determination.

Appeal and reopening of an intermediary determination are both ''issue-specific.'' In order to meet the jurisdictional requirements for appeal to the Board or to the intermediary hearing officer(s), the provider must establish its dissatisfaction with each specific matter at issue in the intermediary determination. We refer readers to section 1878(a) of the Act and regulations at § 405.1835(a)(1) and (b) (Board appeals) and § 405.1811(a)(1) and (b) (intermediary hearing officer appeals). Similarly, § 405.1885(a)(1) provides that the intermediary determination may be reopened ''for findings on matters at issue in a determination.'' We also refer readers to § 405.1887, which provides that a notice of reopening and any revised intermediary determination must specify the findings on matters at issue to be reopened and the particular findings to be revised through reopening, respectively, and § 405.1889(b), which specifies that a provider's appeal rights after reopening are limited to the specific matters altered in the revised intermediary determination.

In many instances, a factual matter arises in, or is determined for, the same fiscal period as the cost reporting period at issue, and such a factual determination may be appealed or reopened as part of that period's intermediary determination. For example, if an IPPS hospital challenges the patient day count used to determine its DSH payment adjustment for its 2010 cost reporting period, the hospital must appeal its DSH patient day count within 180 days of the NPR for the 2010 cost reporting period (and meet the other jurisdictional requirements for appeal to the Board or to the intermediary hearing officer(s), as applicable). Similarly, the hospital would have to request, or the intermediary would have to initiate on its own motion, the reopening of the hospital's 2010 DSH patient day count within 3 years of the NPR for the 2010 cost reporting period.

When the specific matter at issue is a predicate fact that first arose in, or was determined for, a different fiscal period than the cost reporting period in question, our longstanding interpretation and practice is that the pertinent provisions of the statute and regulations provide for review and potential redetermination of such predicate fact only by a timely appeal or reopening of the NPR for the cost reporting period in which the predicate fact first arose or the NPR for the period for which such predicate fact was first determined by the fiscal intermediary. For example, assuming base period costs calculated for the period consisting of the 12 months prior to the hospital's 2002 cost reporting period, if an IPPS-exempt hospital challenges the determination of its 2008 cost reporting period target amount, the hospital could not appeal the determination of the base period predicate facts unless it was within 180 days of the NPR for the base period. Similarly, the hospital would have to request, or the intermediary would have to initiate on its own motion, the reopening of the determination of the hospital's base period costs within 3 years of the NPR for the base year cost reporting period. In addition, the hospital could appeal the determination of the 2008 cost reporting period target rate within 180 days of the NPR for the 2008 cost reporting period and, similarly, could request the reopening of the determination of its 2008 cost reporting period target amount within 3 years of the NPR for the 2008 cost reporting period. There are no additional periods subject to appeal and reopening of such predicate fact unless the predicate facts are redetermined at a later time through an appeal or reopening. Thus, if the same hospital's allowable base period costs or 2008 cost reporting period's target amount was redetermined on appeal or reopening, the hospital could appeal such redetermination within 180 days of the revised NPR for the redetermination of its base period costs or the revised NPR for the redetermination of the 2008 cost reporting period's target amount, respectively. The reopening of such a redetermination (in this example, of the hospital's base period costs or its 2008 cost reporting period's target amount) also could be available within 3 years of the revised NPR for the base period or the 2008 cost reporting period, respectively.

Many reimbursement formulas require the use of predicate facts, where the factual underpinnings of a specific determination of the amount of provider reimbursement first arise in, or are determined for, a different fiscal period than the cost reporting period under review. As discussed above, we believe that predicate facts should be subject to change only through a timely appeal or reopening for the fiscal period in which the predicate fact first arose or the fiscal period in which such fact was first determined by the intermediary. In some instances, a predicate fact from a prior fiscal period is used in a later period with additional information, which is not found in the original cost report or NPR. We believe this kind of determination may be reviewed and redetermined through a timely appeal or reopening of the NPR for the cost reporting period in which the predicate fact was first used (or applied) by the intermediary to determine the provider's reimbursement. However, we recognize exceptions when a particular legal provision (of the Medicare statute, regulations, or CMS rulings) authorizes, as part of a specific reimbursement rule, the review and revision of a predicate fact after the expiration of the 3-year reopening period. For example, the reaudit regulation in § 413.77(a), promulgated to implement section 1886(h)(2) of the Act (which is related to the determination of the average per-resident amount used to calculate reimbursement for graduate medical education (GME) costs), authorizes intermediaries to modify base-period costs solely for purposes of computing the per-resident amount after the hospital's base-period cost report is no longer subject to reopening under § 405.1885. We refer readers to the decision in *Regions Hospital* v. *Shalala,* 522 U.S. 448 (1998), which sustained

the lawfulness of the reaudit regulation (then designated as § 413.86(e)(1)).

We believe that the above-described interpretation of our rules regarding the appeal or reopening of predicate facts furthers the interests of both providers and the agency in maintaining the finality of intermediary determinations. The alternative, of allowing appeal and reopening of a predicate fact after the expiration of the 3-year reopening period, may result in inconsistent intermediary determinations on a reimbursement matter recurring in different fiscal periods for the same provider. An alternative approach of allowing appeal and reopening of a predicate fact beyond the 3-year reopening period could also result in intermediary determinations that are contrary to Medicare law and policy regarding a specific reimbursement matter. As with the target amount example discussed above, reimbursement for various items is premised on a base period cost determination that could affect reimbursement for a given item for many cost reporting periods thereafter. If a provider disputes such a base period cost determination, it can appeal or request reopening of the NPR for the base period. However, unless such an appeal or reopening results in a different finding as to the predicate fact in question, reimbursement for a given provider cost should not be based on one finding about a predicate fact in the base period and a different finding about the same predicate fact for purposes of determining reimbursement in later fiscal periods.

Under our longstanding interpretation and practice, once the 3-year reopening period has expired, neither the provider nor the intermediary is allowed to revisit a predicate fact that was not changed through the appeal or reopening of the cost report for the fiscal period where such predicate fact first arose or for the fiscal period for which such fact was first determined by the intermediary. Further, the application of such facts is subject to change only through a timely appeal or reopening of the cost report for the fiscal period where the predicate fact was first used (or applied) by the intermediary to determine the reimbursement for the provider cost in question. Accordingly, we are proposing to revise § 405.1885 to clarify that, absent a specific statute, regulation, or other legal provision permitting reauditing, revising, or similar actions changing, predicate facts: (1) A predicate fact is subject to change only through a timely appeal or reopening for the fiscal period in which the predicate fact first arose or the fiscal period for which such fact was first determined by the intermediary; and (2) the application of the predicate fact is subject to change only through a timely appeal or reopening of the cost report for the fiscal period in which it was first used (or applied) by the intermediary to determine the provider's reimbursement.

We note that a recent court decision conflicts with our settled interpretation of the regulations for provider appeals and cost report reopening. In *Kaiser Foundation Hospitals* v. *Sebelius,* 708 F.3d 226 (D.C. Cir. 2013), the court held that providers could appeal predicate facts used to determine their reimbursement in later fiscal periods even though such predicate facts were not timely appealed or reopened for the periods when they first arose or were determined by the intermediary nor was the application of those facts to the periods when those facts were first used by the intermediary to determine the providers' reimbursement. The predicate facts at issue in this case were the teaching hospitals' resident full-time equivalent (FTE) counts for their 1996 cost reporting periods, which, as required by section 1886(h)(4)(F)(i) of the Act, were used to calculate the statutory cap on residents for GME cost reimbursement for the first time in the hospitals' 1998 cost reporting periods. The providers could have challenged their resident FTE counts through timely appeals or reopening of their 1996 fiscal period NPRs, and they could have challenged the calculation of their resident caps through timely appeals or reopening of their 1998 fiscal period NPRs, the first time the caps were applied. Instead, the hospitals appealed their resident caps as applied to later cost reporting periods. The court held that the definition of ''intermediary determination'' under § 405.1801(a)(1), which is incorporated in the reopening rules at § 405.1885(a)(1), did not include factual findings, standing alone, where the providers made no attempt to challenge their GME cost reimbursement for their 1996 or 1998 fiscal periods due to the expiration of the 180-day appeal period and the 3-year period for reopening. Because the providers were not challenging the total amount of program reimbursement paid for their 1996 or 1998 fiscal periods, the court concluded that the intermediary determinations for those periods were not at issue and thus the 3-year limitation on reopening was not applicable.

We disagree with the court's decision, which we believe is contrary to our reopening regulations at § 405.1885(a), and the corresponding appeals regulations (discussed above), and which necessitates our proposed clarification of the regulations. As noted above, we are proposing to revise § 405.1885 to clarify that the specific ''matters at issue in a determination'' that are subject to the reopening rules include factual findings for one fiscal period that are predicate facts for later fiscal periods. The general 3-year reopening period applies to findings about such predicate facts and the reopening period is calculated separately for each finding about a predicate fact. We note that this proposed revision of § 405.1885 would apply to all Medicare reimbursement determinations, and not only to GME payment, which was the particular issue in *Kaiser Foundation Hospitals* v. *Sebelius.* Because this proposed revision clarifies longstanding agency policy, we are proposing that it be effective for any intermediary determination issued on or after the effective date of the final rule, and for any appeals or reopenings (or requests for reopening) that are pending on or after the effective date of the final rule, even if the intermediary determination (at issue in such an appeal or reopening) preceded the effective date of the final rule. We believe the proposed revision is not impermissibly retroactive in effect because the proposal simply clarifies longstanding agency policy and practice, and is procedural in nature. We refer readers, for example, to *Heimmermann* v. *First Union Mortgage Corp.,* 305 F.3d 1257, 1260–61 (11th Cir. 2002) (a rule clarifying the law, especially in an unsettled or confusing area of the law, is not a substantive change in the law, and thus the rule may apply to matters that preceded issuance of the rule). However, if the proposed revision to § 405.1885 were deemed a retroactive application of a substantive change to a regulation, section 1871(e)(1)(A) of the Act permits retroactive application of a substantive change to a regulation if the Secretary determines that such retroactive application is necessary to comply with statutory requirements or that failure to apply the change retroactively would be contrary to the public interest. We have determined that retroactive application of the proposed revision to § 405.1885 is necessary to ensure compliance with the 3-year limit on reopening and with various statutory payment provisions such as the target amount (under section 1886(b) of the Act) and the cap on residents for GME cost reimbursement (under section 1886(h)(4)(F)(i) of the Act). We have further determined that it would be in the public interest to apply

the proposed revision to intermediary determinations, appeals, and reopenings (including requests for reopening) that are pending on or after the effective date of the final rule. Not applying the proposed revisions to pending intermediary determinations, appeals, and reopenings would undermine the 3-year limit on reopening and the interests of both the Medicare program and Medicare providers in the finality of reimbursement determinations, and would be inconsistent with the statutory scheme.

Finally, although we have provided proposed revisions only to § 405.1885, in order to clarify our regulations in accordance with this proposal, we are considering making similar changes regarding predicate facts to the regulations governing intermediary appeals at § 405.1811 and appeals to the Board at § 405.1835. We are requesting public comments with respect to amending the language of these additional regulations for appeals before the intermediary and the Board.

XX. Files Available to the Public via the Internet

We are proposing to create new Addendum P—Proposed OPPS Items and Services That Will be Packaged for CY 2014.

The Addenda of the proposed rules and the final rules with comment period will be published and available only via the Internet on the CMS Web site. To view the Addenda of this proposed rule pertaining to the proposed CY 2014 payments under the OPPS, go to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html* and select ''1601–P'' from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled ''2014 OPPS 1601–P Addenda'' at the bottom of the page.

To view the Addenda of this proposed rule pertaining to the proposed CY 2014 payments under the ASC payment system, go to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html* and select ''1601–P'' from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled ''Addendum AA, BB, DD1 and DD2,'' and ''Addendum EE'' at the bottom of the page.

XXI. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comments on each of the issues outlined above for the information collection requirements discussed below.

B. Requirements in Regulation Text

1. Proposed Changes to the Outcome Measure Requirement for OPOs

In section XVI. Of this proposed rule, we discussed our proposal to modify the outcome measures requirement for OPOs set forth at § 486.318. Currently, OPOs are required to meet all three outcome measures in that section or they are automatically decertified. We are proposing to modify that requirement so that OPOs will meet the outcome measures requirement if they meet two out of the three outcome measures.

Based on our experience with OPOs and historical data concerning how many OPOs typically fail to meet one of the outcome measures, we believe that there would be about five OPOs that would fail to meet one of the outcome measures. Our proposal would result in those five OPOs meeting the outcome measures requirement and not being automatically de-certified. Therefore, these five OPOs would not have to perform the ICRs under this section, which would be the time and resources needed to go through the appeals process in an attempt to secure a reversal of the decertification.

The ICRs that an OPO would be required to expend would depend upon how it chose to handle the decertification. An OPO may choose to not engage in the appeals process and merge with another OPO prior to the effective date of the decertification. Other OPOs would likely choose to take advantage of the appeals process, which would begin with reconsideration at the regional administrator level. It is likely that an OPO would expend considerable resources during the reconsideration and, if that was unsuccessful, a hearing before a CMS hearing officer. We believe both would require considerable time and other resources from the OPO's senior staff and legal counsel. We also believe that those OPOs that went onto a hearing would expend considerably more resources than those that received a reversal of their decertification at the reconsideration. While we do not have a reliable estimate on how much these OPOs would save due to the numerous unknown variables, we are confident that these OPOs would sustain a significantly positive effect from not being automatically de-certified as is currently required under the OPO CfCs. In addition, under 5 CFR 1320.3(c), a ''collection of information''' does not include requirements imposed on fewer than 10 entities. Therefore, the requirements of this section are not subject to the PRA.

2. Proposed Changes to the Medicare Fee-for-Service EHR Incentive Program

In section XVIII. of this proposed rule, we are proposing to revise 42 CFR 495.4 to provide a special method for making hospital-based determinations for 2103 only in the cases of those EPs who reassign their benefits to Method II CAHs. We also are proposing a minor clarification to the regulations at § 495.104(c)(2) concerning the cost reporting period to be used in determining final EHR payments for hospitals. We refer readers to the Stage 1 (75 FR 44536 ff) and Stage 2 (77 FR 54126 ff) final rules for the Medicare EHR Incentive Program for the discussions of the burden of the information collection requirements of the Medicare Fee-for-Service EHR Incentive Program. Our proposals in this rule do not modify or increase the information collection requirements of the program in any way.

C. Associated Information Collections Not Specified in Regulatory Text

In this proposed rule, we make reference to proposed associated information collection requirements that are not discussed in the regulation text contained in this proposed rule. The following is a discussion of those requirements.

1. Hospital OQR Program

As we stated in section XIV. of the CY 2012 OPPS/ASC final rule with comment period, the Hospital OQR Program has been generally modeled after the quality data reporting program for the Hospital IQR Program. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72111 through 72114), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74549 through 74554) and the CY 2013 OPPS/ASC final rule with comment period (77 FR 68527 through 68532) for detailed discussions of the Hospital OQR Program information collection requirements we have previously finalized.

a. Hospital OQR Program Requirements for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68531) for a discussion on the burden of the information collection requirements of the previously adopted Hospital OQR Program measures for the CY 2015 payment determination. We are not proposing to add any additional measures for the CY 2015 payment determination and subsequent years, so there will be no change in our previous burden estimate.

We note that we had previously suspended data collection for the OP–19 measure and deferred data collection for the OP–24 measure.

In addition, we are proposing to codify existing policies related to program participation and withdrawal, data submission, program waivers, data validation, and the reconsideration process. Because we are only codifying existing policies, we do not anticipate any additional burden to hospitals based on this proposal affecting the CY 2015 payment determination or subsequent years.

b. Web-Based Measures for the CY 2016 Payment Determination and Subsequent Years

For the CY 2016 payment determination and subsequent years, we are proposing to add five measures to the program with data collection beginning during CY 2014. We are soliciting public comment on the impact of adding these measures and requiring data submission of aggregate data via a Web-based tool for four chart-abstracted measures. Hospitals will vary greatly as to the number of cases per HOPD due to specialization. However, we estimate based on our past experiences with chart-abstracted measures that each participating hospital will spend 35 minutes per case to collect and submit the data, and that the estimated burden associated with there being one case per hospital would be 1,924 hours (3,300 hospitals × 0.583 hours per hospital).

In addition, HOPDs will incur a financial burden associated with chart abstraction and data submission for these four proposed measures. We estimate the burden associated with there being one case per hospital would be $57,717 (3,300 hospitals × $30.00 per hour × 0.583 hours).

For the CY 2016 payment determination, the burden associated with Hospital OQR Program procedures is the time and effort associated with collecting and submitting the data on the measures. For the chart-abstracted measures where patient-level data is submitted directly to CMS, we estimate that there will be approximately 3,300 respondents per year. For hospitals to collect and submit this information, we estimate it will take 35 minutes per submitted case. Based upon the data submitted for the CY 2012 and CY 2013 payment determinations, we estimate there will be a total of 1,679,700 cases per year, approximately 509 cases per year per hospital. Therefore, the estimated annual hourly burden associated with the aforementioned data submission requirements for the chart-abstracted data is 979,265 hours (1,679,700 cases per year × 0.583 hours per case).

In addition, HOPDs will incur a financial burden associated with chart abstraction and data submission where patient-level data are submitted directly to CMS. We estimate the burden associated with these measures is $29,377,953 (1,679,700 cases per year × $30.00 per hour × 0.583 hours per case).

For the measures where data is submitted to CMS via a Web-based online tool (OP–12, 17, 22, 25, 26, 28, 29, 30, 31) located on a CMS Web site, we estimate that each participating hospital would spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with these measures 4,960 hours (3,300 hospitals × 0.167 hours per measure × 9 measures per hospital) in CY 2015.

In addition, HOPDs will incur a financial burden associated with chart abstraction and data submission for these 9 measures. We estimate that the financial burden associated with these measures would be $148,797 (3,300 hospitals × $30.00 per hour × 0.167 hours per measure x 9 measures).

For the NHSN HAI measure: Influenza Vaccination Coverage among Healthcare Personnel, we estimate that the total annual burden associated with this measure for an HOPD for data submission would be 27,555 hours (3,300 hospitals × 0.167 hour per response for 50 workers per hospital).

In addition, HOPDs will incur a financial burden associated with data submission for this measure. We estimate that the financial burden associated with these measures would be $826,650 ($30.00 per hour × 27,555 hours).

We invite public comment on the burden associated with these information collection requirements.

c. Hospital OQR Program Validation Requirements for the CY 2015 Payment Determination and Subsequent Years

We are not proposing to make any changes to our validation procedures. As a result, the burden associated with the validation procedures for the CY 2015 payment determination as proposed is the same as previously finalized for CY 2014 in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68531) and is the time and effort necessary to submit validation data to a CMS contractor. We estimate that it would take each of the sampled hospitals approximately 12 hours to comply with these data submission requirements. To comply with the requirements, we estimate each hospital would submit up to 48 cases for the affected year for review. All selected hospitals must comply with these requirements each year, which would result in a total of up to 24,000 charts being submitted by the sampled hospitals (500 selected hospitals x 48 cases per hospital). The estimated annual burden associated with the data validation process for the CY 2015 payment determination is approximately 6,000 hours.

In addition, HOPDs will incur a financial burden associated with the required data abstraction and data submission for this measure. We estimate that the financial burden associated with this measure would be $180,000 ($30.00 per hour × 6,000 hours).

These requirements are currently approved under OCN: 0938–1109. This approval expires on October 31, 2013.

We invite public comment on the burden associated with data validation information collection procedures.

d. Hospital OQR Program Reconsideration and Appeals Procedures

In section XIII.I. of this proposed rule, for the CY 2015 payment determination and subsequent years, we are proposing a minor change to the reconsideration request process to ensure our deadline

for these requests will always fall on a business day. We also are proposing to codify our reconsideration request process at 42 CFR 419.46(h).

While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

2. ASCQR Program Requirements

a. Claims-Based Measures for the CY 2014 Payment Determination

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532), we discussed the information collection requirements for the five claims-based measures (four outcome measures and one process measure) to be used for the CY 2014 payment determination. The five measures are: (1) Patient Burn (NQF #0263); (2) Patient Fall (NQF #0266); (3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); (4) Hospital Transfer/Admission (NQF #0265); and (5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264). We collected quality measure data for the five claims-based measures using QDCs placed on submitted claims for services furnished from October 1, 2012 through December 31, 2012 that were paid by the contractor by April 30, 2013.

Approximately 71 percent of ASCs participated in Medical Event Reporting, which included reporting on the first four claims-based measures, which are outcome measures. Between January 1995 and December 2007, ASCs reported 126 events, an average of 8.4 events per year (Florida Medical Quality Assurance, Inc. and Health Services Advisory Group: Ambulatory Surgical Center Environmental Scan (July 2008) (Contract No. GS–10F–0096T)). We estimated the burden to report QDCs for these 4 claims-based outcome measures to be nominal due to the small number of cases. Based on the data above, extrapolating from 71 percent to 100 percent of ASCs reporting, there would be an average of 11.8 events per year or less than 1 case per month per ASC.

For the claims-based process measure, Prophylactic IV Antibiotic Timing, we also estimated the burden associated with submitting QDCs to be nominal because few procedures performed by ASCs will require prophylactic antibiotic administration.

We invite public comment on the burden associated with these information collection requirements.

b. Claims-Based and Web-Based Measures for the CY 2015 and CY 2016 Payment Determinations

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532), we discussed the information collection requirements for the measures to be used for the CY 2015 and CY 2016 payment determinations. For the CY 2015 payment determination, we finalized the retention of the five measures we adopted for the CY 2014 payment determination, and we added two structural, Web-based, measures: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures (76 FR 74504 through 74509). For the CY 2016 payment determination, we finalized the retention of the seven measures for the CY 2015 payment determination and added Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (76 FR 74509).

Based on our data for CY 2014 payment determinations above for claims-based measures, extrapolating to 100 percent of ASCs reporting, there would be an average of 11.8 events per year. Thus, we estimated the burden to report QDCs on this number of claims per year for the first four claims-based outcome measures to be nominal due to the small number of cases (approximately one case per month per ASC) for the CY 2015 and CY 2016 payment determinations. We estimated the burden associated with submitting QDCs for the fifth measure to be nominal as well, as discussed above.

For the CY 2015 payment determination, for the Web-based measures, ASCs will enter required information using a Web-based collection tool between July 1, 2013 and August 15, 2013. For the Safe Surgery Checklist Use measure, we estimated that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs × 1 measure × 0.167 hours per ASC). For the CY 2015 payment determination, we estimate that, for the ASC Facility Volume Data on Selected ASC Surgical Procedures measure, each participating ASC would spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs × 1 measure 0.167 hours per ASC).

For the CY 2016 payment determination, in this proposed rule we are proposing that ASCs would report data for the Safe Surgery Checklist measure and the ASC Volume Data on Selected ASC Surgical Procedures measure between January 1, 2015 and August 15, 2015 for services furnished between January 1, 2014 and December 31, 2014. For the Safe Surgery Checklist measure for the CY 2016 payment determination, we estimate that each participating ASC would spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs × 1 measure × 0.167 hours per ASC). For the CY 2016 payment determination, for the ASC Volume Data on Selected ASC Surgical Procedures measure, we estimate that each participating ASC would spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs × 1 measure × 0.167 hours per ASC).

For the CY 2016 payment determination, for the NHSN HAI measure: Influenza Vaccination Coverage among Healthcare Personnel, we estimate that the total annual burden associated with this measure for ASCs, including NHSN registration (5,260 ASCs × 0.083 hour per facility = 437 hours) and data submission (5,260 ASCs × 0.167 hour per response for 20 workers per facility = 17,568), will be 18,005 hours. This estimate is based upon burden estimates from the CDC (OMB No. 0920–0666) and reported numbers for the average number of workers per ASC.

For the CY 2016 payment determination, in this proposed rule, we are proposing to add four measures to the program with data collection to begin during CY 2014 and submission to be via a Web-based tool. As chart-abstracted measures, we estimate that each participating ASC would spend 35 minutes per case to collect and submit the data, making the total estimated burden for ASCs with a single case per ASC would be 3,067 hours (5,260 ASCs × 0.583 hours per case per ASC). We expect that ASCs would vary greatly as to the number of cases per ASC due to ASC specialization.

In addition, ASCs would incur a financial burden associated with chart abstraction and data submission for these four proposed measures. We estimate that, for a per chart abstracted case, an ASC would incur a cost of $91,997 (5,260 ASCs × $30.00 per hour × 0.583 hours). We are soliciting public comment on the impact of adding these measures and requiring data submission.

We invite public comment on the burden associated with these information collection requirements.

c. Program Administrative Requirements and QualityNet Accounts; Extraordinary Circumstance and Extension Requests; Reconsideration Requests

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized our proposal to consider an ASC to be participating in the ASCQR Program for the CY 2014 payment determination if the ASC includes QDCs specified for the program on their CY 2012 claims relating to the finalized measures.

In the FY 2013 IPPS/LTCH PPS final rule, we finalized, for the CY 2015 payment determination and subsequent years, that once an ASC submits any quality measure data, it would be considered to be participating in the ASCQR Program. Once an ASC submits quality measure data indicating its participation in the ASCQR Program, in order to withdraw, an ASC must complete and submit an online form indicating that it is withdrawing from the program.

For the CY 2015 payment determination and subsequent years, if the ASC submits quality measure data, there is no additional action required by the ASC to indicate participation in the program. The burden associated with the requirements to withdraw from the program is the time and effort associated with accessing, completing, and submitting the online form. Based on the number of hospitals that have withdrawn from the Hospital OQR Program over the past 4 years, we estimated that 2 ASCs would withdraw per year and that an ASC would expend 30 minutes to access and complete the form, for a total burden of 1 hour per year.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53638 through 53639), we finalized for the CY 2015 payment determination the requirement that ASCs to identify and register a QualityNet administrator in order to set up accounts necessary to enter structural measure data. We estimated that, based upon previous experience with the Hospital OQR Program, it would take an ASC 10 hours to obtain, complete, and submit an application for a QualityNet administrator and then set up the necessary accounts for structural measure data entry. We estimated the total burden to meet these requirements to be 52,600 hours (10 hours × 5,260 ASCs). The financial burden associated with these requirements is estimated to be $1,578,000 ($30.00 per hour × 52,600 hours).

In the FY 2013 IPPS/LTCH PPS final rule, we adopted a process for an extension or waiver for submitting information required under the program due to extraordinary circumstances that are not within the ASC's control. We are requiring that an ASC would complete a request form that would be available on the QualityNet Web site, supply requested information, and submit the request. The burden associated with these requirements is the time and effort associated with gathering required information as well as accessing, completing, and submitting the form. Based on the number of ASCs that have submitted a request for an extension or waiver from the ASCQR Program over the past year, we estimate that 200 ASCs per year would request an extension or waiver and that an ASC would expend 2 hours to gather required information as well as access, complete, and submit the form, for a total burden of 400 hours per year. This estimate takes into account continued billing and claims processing issues.

We also adopted a reconsideration process that would apply to the CY 2014 payment determination and subsequent payment determination years under the ASCQR Program. While there is burden associated with an ASC filing a reconsideration request, the regulations at 5 CFR 1320.4 for the Paperwork Reduction Act of 1995 exclude data collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

We invite public comment on the burden associated with these information collection requirements.

3. Hospital VBP Program Requirements

In section XIV. of this proposed rule, for the Hospital VBP Program, we are proposing to allow hospitals to request an independent CMS review that would be an additional appeal process beyond the existing review and corrections process (77 FR 53578 through 53581 and 76 FR 74544 through 74547) and appeal process codified at 42 CFR 412.167.

While there is burden associated with a hospital requesting an independent CMS review, the regulations at 5 CFR 1320.4 for the Paperwork Reduction Act of 1995 exclude collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

We invite public comment on the burden associated with these information collection requirements.

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–1601–P; Fax: (202) 395–6974; or Email: *OIRAsubmissions_@omb.eop.gov*

XXII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXIII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104–121) (5 U.S.C. 804(2)). This section of the proposed rule contains the impact and other economic analyses for the provisions that we are proposing.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as an ''economically'' significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104–121). Accordingly, the proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this proposed rule. In this proposed rule, we

are soliciting public comments on the regulatory impact analysis provided.

2. Statement of Need

This proposed rule is necessary to update the Medicare hospital OPPS rates. It is necessary to propose to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2014. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2012, through and including December 31, 2012, and updated cost report information.

For CY 2014, we are proposing to continue the current payment adjustment for rural SCHs, including EACHs. In addition, section 10324 of the Affordable Care Act, as amended by HCERA, authorizes a wage index of 1.00 for certain frontier States. Section 1833(t)(17) of the Act requires that subsection (d) hospitals that fail to meet quality reporting requirements under the Hospital OQR Program incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor. In this proposed rule, we are proposing to implement these payment provisions. Also, we list the 15 drugs and biologicals in Table 19 that we are proposing to remove from pass-through payment status for CY 2014.

This proposed rule is also necessary to update the ASC payment rates for CY 2014, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2014. Because the ASC payment rates are based on the OPPS relative payment weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, because the services provided in ASCs are identified by HCPCS codes that are reviewed and revised either quarterly or annually, depending on the type of code, it is necessary to update the ASC payment rates annually to reflect these changes to HCPCS codes. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less frequently than every 2 years. Sections 1833(i)(2)(D)(iv) and 1833(i)(7) of the Act authorize the Secretary to implement a quality reporting system for ASCs in a manner so as to provide for a reduction of 2.0 percentage points in any annual update with respect to the year involved for ASCs that fail to meet the quality reporting requirements. For CY 2014, we discuss the impacts associated with this payment reduction in section XV.C. of this proposed rule.

3. Overall Impacts for the Proposed OPPS and ASC Payment Provisions

We estimate that the effects of the proposed OPPS payment provisions would result in expenditures exceeding $100 million in any 1 year. We estimate that the total increase from the proposed changes in this proposed rule in Federal government expenditures under the OPPS for CY 2014 compared to CY 2013 would be approximately $600 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the proposed OPPS expenditures for CY 2014 would be approximately $4.372 billion higher, relative to expenditures in CY 2013. Because this proposed rule is ''economically significant'' as measured by the $100 million threshold, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 39 displays the redistributional impact of the proposed CY 2014 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through estimates, and the application of the frontier State wage adjustment for CY 2014) would increase total OPPS payments by 1.8 percent in CY 2014. The proposed changes to the APC weights, the proposed changes to the wage indices, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because these proposed changes to the OPPS would be budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the proposed total change in payments between CY 2013 and CY 2014, considering all proposed payments, including proposed changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the proposed OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G) and 1833(t)(17) of the Act, would increase total estimated OPPS payments by 1.8 percent.

We estimate the total increase (from proposed changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in expenditures under the ASC payment system for CY 2014 compared to CY 2013 to be approximately $133 million. Because the provisions for the ASC payment system are part of a proposed rule that is ''economically significant'' as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the proposed changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of the proposed rule. Tables 40 and Table 41 of this proposed rule display the redistributional impact of the proposed CY 2014 changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Estimated Effects of Proposed OPPS Changes in This Proposed Rule

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2014 policy changes on various hospital groups. We post on the CMS Web site our proposed hospital-specific estimated payments for CY 2014 with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1601–P'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 39 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose

claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our proposed policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service-mix, or number of encounters. In this proposed rule, we are soliciting public comment and information about the anticipated effects of our proposed changes on providers and our methodology for estimating them. Any public comments that we receive will be addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of Proposed OPPS Changes on Hospitals

Table 39 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the proposed change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers because we include CMHCs in our weight scaler estimate. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 39 and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2013, we are paying CMHCs under APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), and we are paying hospitals for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). We display separately the impact of our proposed updates on CMHCs, and we discuss its impact on hospitals as part of our discussion of the hospital impacts.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this proposed rule. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase for FY 2014 is 2.5 percent (78 FR 27497). Section 1833(t)(3)(F)(i) of the Act reduces that 2.5 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.4 percentage points for FY 2014 (which is also the proposed MFP adjustment for FY 2014 in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27786); and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act further reduce the market basket percentage increase by 0.3 percentage points, resulting in the proposed OPD fee schedule increase factor of 1.8 percent, which we are proposing to use in the calculation of the proposed CY 2014 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.00. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2014 estimates in Table 39.

To illustrate the impact of the proposed CY 2014 changes, our analysis begins with a baseline simulation model that uses the CY 2013 relative payment weights, the FY 2013 final IPPS wage indices that include reclassifications, and the final CY 2013 conversion factor. Table 39 shows the estimated redistribution of the proposed increase in payments for CY 2014 over CY 2013 payments to hospitals and CMHCs as a result of the following factors: APC reconfiguration and recalibration for CY 2014 compared to CY 2013 payments (Column 2); the marginal impact of our packaging proposals other than packaging for clinical laboratory tests (Column 3); the marginal impact of our proposal to package clinical laboratory services (Column 4); the combined impact of all of our packaging proposals and proposed APC reconfiguration and recalibration for CY 2014, compared to CY 2013 payments (Column 5: the combined effect of columns 2, 3 and 4); the proposed wage indices and the rural adjustment (Column 6); the combined impact of proposed APC recalibration, the proposed wage indices and rural adjustment, and the proposed OPD fee schedule increase factor update to the conversion factor (Column 7); the combined impact of proposed APC recalibration, the proposed wage indices and rural adjustment, the proposed conversion factor update, and the proposed CY 2014 frontier State wage index adjustment (Column 8); and the estimated impact taking into account all proposed payments for CY 2014 relative to all payments for CY 2013 (Column 9), including the impact of proposed changes in estimated outlier payments and proposed changes to the pass-through payment estimate.

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are not proposing to make any changes to the policy for CY 2014. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2014 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also would depend on changes in volume, practice patterns, and the mix of services billed between CY 2013 and CY 2014 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed OPPS rates for CY 2014 would have a positive effect for providers paid under the OPPS, resulting in a 1.8 percent estimated increase in Medicare payments. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs suggest that these proposed changes would result in a 1.8 percent estimated increase in Medicare payments to all other hospitals. Those estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 39 shows the total number of facilities (3,953), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2012

hospital outpatient and CMHC claims data to model CY 2013 and CY 2014 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2013 or CY 2014 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a disproportionate share (DSH) variable for hospitals not participating in the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number (3,791) of OPPS hospitals, excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on 100 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration

Column 2 shows the estimated effect of the reconfiguration and recalibration of the APCs from CY 2013 to CY 2014 excluding the CY 2014 OPPS packaging proposals. Outpatient laboratory services paid at CLFS rates are included on both sides of the comparison. We estimate that most hospitals would not experience significant changes in payment rates from the APC recalibration alone, though we estimate that Puerto Rico would experience a 4.3 percent increase in payments and that low volume rural hospitals (measured by lines of services) would experience a 1.8 percent payment decrease.

Column 3: APC Recalibration With CY 2014 Packaging Proposals Other than Outpatient Laboratory Services

Column 3 shows the estimated impact of the APC recalibration from CY 2013–2014 with our proposed packaging policies other than packaging for outpatient laboratory services currently paid at CLFS rates. Outpatient laboratory services paid at CLFS rates are included on both sides of the comparison. Hospitals that specialize in a limited set of services would experience the most significant changes in payment. Urban hospitals with less than 21,000 service lines would experience estimated payment decreases ranging from 0.4 to 1.9 percent. Hospitals where DSH data are not available (specialized hospitals not paid under the IPPS) would experience estimated payment decreases of 1.4 percent.

Column 4: APC Recalibration With CY 2014 Outpatient Laboratory Services Packaging Proposal

Column 4 shows the estimated effect of APC recalibration plus our proposed policy for packaging outpatient laboratory services paid at CLFS rates. Outpatient laboratory services paid at CLFS rates are included in the comparison. It does not include estimated effects for other packaging proposals. We estimate that smaller rural hospitals, particularly in the mid-Atlantic region, would experience the most significant payment changes related to the laboratory packaging policy proposal, as they likely furnish more ancillary laboratory services relative to other services than larger hospitals. We estimate that rural hospitals overall would experience a 1.3 percent decrease in payment, and rural hospitals with 100 or fewer beds would experience payment decreases between 1.9 and 3.5 percent. Urban hospitals overall would experience limited estimated payment increases ranging from 0.1 to 0.3 percent.

Column 5: APC Recalibration With All Proposed Changes

Column 5 shows the combined effects of the proposed reconfiguration, recalibration, and other policies (such as proposing to set payment for separately payable drugs and biologicals at the statutory default of ASP+6), plus our proposals to package outpatient laboratory services and other services for CY 2014. We modeled the effect of the APC recalibration changes by varying only the relative payment weights (the final CY 2013 relative weights versus the proposed CY 2014 relative weights calculated using the service-mix and volume in the CY 2012 claims used for this proposed rule) and calculating the percent difference in the relative weight. Column 5 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights.

Overall, we estimate that proposed changes in APC reassignment and recalibration across all services paid under the OPPS, together with our proposed packaging policies, would slightly increase payments to urban hospitals by 0.1 percent. We estimate that rural hospitals would experience a decrease in payments of 0.7 percent.

Classifying hospitals according to teaching status, we estimate that the APC recalibration together with our proposed packaging policies would lead to a payment increase of 1.2 percent for major teaching hospitals. We estimate that nonteaching hospitals would experience a decrease of 0.6 percent. Classifying hospitals by type of ownership suggests that voluntary, proprietary, and governmental hospitals would experience changes ranging from a decrease of 0.6 percent to an increase of 0.2 percent as a result of the APC recalibration and proposed packaging policies.

Column 6: New Wage Indices and the Effect of the Rural and Cancer Hospital Adjustments

Column 6 demonstrates the combined budget neutral impact of proposed APC recalibration; the proposed wage index update; the proposed rural adjustment; and the proposed cancer hospital payment adjustment. We modeled the independent effect of the proposed budget neutrality adjustments and the proposed OPD fee schedule increase factor by using the relative payment weights and wage indices for each year, and using a CY 2013 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indices.

Column 6 reflects the independent effects of the proposed updated wage indices, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the proposed frontier State wage index adjustment, which is not budget neutral and is included in Column 8. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are not proposing to make any changes to the policy for CY 2014. The differential impact between the CY 2013 cancer hospital payment adjustment and the proposed CY 2014 cancer hospital payment adjustment would have a minimal effect on the budget neutral adjustment to the conversion factor. We modeled the independent effect of updating the wage indices by varying only the wage indices, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the proposed CY 2014 scaled weights and a

CY 2013 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indices between CY 2013 and CY 2014. This column estimates the impact of applying the proposed FY 2014 IPPS wage indices for the proposed CY 2014 OPPS without the influence of the frontier State wage index adjustment, which is not budget neutral. The proposed frontier State wage index adjustment is reflected in the combined impact shown in Column 8. We are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2014, as described in section II.E. of this proposed rule. We estimate that the combination of updated wage data and nationwide application of rural floor budget neutrality would redistribute payment among regions. We also are proposing to update the list of counties qualifying for the section 505 out-migration adjustments.

Overall, we estimate that as a result of the proposed updated wage indices and the proposed rural adjustment, urban hospitals would experience no change from CY 2013 to CY 2014. However, rural hospitals would experience an estimated decrease of 0.3 percent. Urban hospitals in the New England, Mid Atlantic, and Pacific regions and in Puerto Rico would experience the most significant payment changes of 0.6 to 0.7 percent increases. Regionally, the proposed changes would range from a decrease of 0.6 in the rural East South Central region to an increase of 0.7 percent in the rural Pacific region.

Column 7: All Proposed Budget Neutrality Changes Combined With the Proposed OPD Fee Schedule Increase

Column 7 demonstrates the cumulative impact of the proposed budget neutral adjustments from Columns 5 and 6 and the proposed OPD fee schedule increase factor of 1.8 percent. We estimate that, for some hospitals, the addition of the proposed OPD fee schedule increase factor of 1.8 percent would mitigate the impacts created by the proposed budget neutrality adjustments made in Columns 5 and 6.

Most classes of hospitals would receive an increase that is in line with the proposed 1.8 percent overall increase after the update is applied to the budget neutrality adjustments. The largest rural hospitals by number of beds (200+ beds) would experience payment increases of 1.4 percent. Proprietary, voluntary, and government hospitals would experience payment increases ranging from 1.0 to 2.0 percent. Hospitals in Puerto Rico would receive an estimated payment increase of 6.3 percent. The rural Mid-Atlantic region would experience a 0.4 percent payment decrease, while the urban Mid-Atlantic region would experience a 2.8 percent payment increase. Classified by teaching status, nonteaching hospitals would experience a small payment increase of 1.1 percent, with minor and major teaching hospitals experiencing increases ranging from 1.8 to 3.2 percent, respectively.

Column 8: All Proposed Adjustments With the Proposed Frontier State Wage Index Adjustment

This column shows the impact of all proposed budget neutrality adjustments, application of the proposed 1.8 percent OPD fee schedule increase factor, and the nonbudget neutral impact of applying the proposed frontier State wage adjustment (that is, the proposed frontier State wage index change in addition to all proposed changes reflected in Column 7). This column differs from Column 7 solely based on application of the proposed nonbudget neutral frontier State wage index adjustment.

In general, we estimate that all facilities and all hospitals would experience a combined increase of 1.9 percent due to the proposed nonbudget neutral frontier State wage index adjustment. The index would only affect urban hospitals in the West North Central and Mountain regions. Urban hospital in those regions would experience estimated increases of 4.5 percent (West North Central) and 2.3 percent (Mountain) that are attributable to the proposed frontier State wage index and the OPD fee schedule increase factor, and rural hospitals would experience estimated increases of 3.5 percent (West North Central) and 3.4 percent (Mountain) that are attributable to the proposed frontier State wage index and the OPD fee schedule increase factor.

Column 9: All Proposed Changes for CY 2014

Column 9 depicts the full impact of the proposed CY 2014 policies on each hospital group by including the effect of all of the proposed changes for CY 2014 and comparing them to all estimated payments in CY 2013. Column 9 shows the combined budget neutral effects of Column 5 and 6; the proposed OPD fee schedule increase; the impact of the proposed frontier State wage index adjustment; the impact of estimated OPPS outlier payments as discussed in section II.G. of this proposed rule; the proposed change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII. of this proposed rule); and the impact of decreasing the estimate of the percentage of total OPPS payments dedicated to transitional pass-through payments. Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2013 update (and assumed, for modeling purposes, to be the same number for CY 2014), we included 34 hospitals in our model because they had both CY 2012 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2014 would increase payments to all providers by 1.8 percent for CY 2014. We modeled the independent effect of all proposed changes in Column 9 using the final relative payment weights for CY 2013 and the proposed relative payment weights for CY 2014. We used the final conversion factor for CY 2013 of $71.313 and the proposed CY 2014 conversion factor of $72.728 discussed in section II.B. of this proposed rule.

Column 9 contains simulated outlier payments for each year. We used the one year proposed charge inflation factor used in the proposed FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27767) of 4.85 percent (1.0485) to increase individual costs on the CY 2012 claims, and we used the most recent overall CCR in the April 2013 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2013. Using the CY 2012 claims and a 4.85 percent charge inflation factor, we currently estimate that outlier payments for CY 2013, using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $2,025 should be approximately 1.2 percent of total payments. The estimated current outlier payments of 1.2 percent are incorporated in the comparison in Column 9. We used the same set of claims and a proposed charge inflation factor of 9.93 percent (1.0993) and the CCRs in the April 2013 OPSF, with an adjustment of 0.9732, to reflect relative changes in cost and charge inflation between CY 2012 and CY 2014, to model the proposed CY 2014 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $2,775.

We estimate that the anticipated change in payment between CY 2013 and CY 2014 for the hospitals failing to meet the Hospital OQR Program requirements would be negligible. Overall, we estimate that facilities would experience an increase of 1.8 percent under this proposed rule in CY

2014 relative to total spending in CY 2013. This projected increase (shown in Column 9) of Table 39 reflects the proposed 1.8 percent OPD fee schedule increase factor, with 0.13 percent for the proposed change in the pass-through estimate between CY 2013 and CY 2014, less 0.2 percent for the difference in estimated outlier payments between CY 2013 (1.2 percent) and CY 2014 (1.0 percent), less 0.1 percent due to the frontier adjustment in CY 2013, plus 0.1 percent due to the proposed frontier State wage index adjustment in CY 2014. When we exclude cancer and children's hospitals (which are held harmless to their pre-BBA amount) and CMHCs, the estimated update increases to 1.8 percent after rounding. We estimate that the combined effect of all proposed changes for CY 2014 would increase payments to urban hospitals by 2.0 percent.

Overall, we estimate that rural hospitals would experience a 0.9 percent increase as a result of the combined effects of all proposed changes for CY 2014. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services would experience an increase of 2.2 percent and rural hospitals that bill 5,000 or more lines of OPPS services would experience increases ranging from 0.9 to 2.4 percent.

Among teaching hospitals, we estimate that the impacts resulting from the combined effects of all proposed changes would include an increase of 3.1 percent for major teaching hospitals and 1.2 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 1.8 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 2.1 percent, proprietary hospitals would experience an increase of 1.3 percent, and governmental hospitals would experience an increase of 1.0 percent.

TABLE 39—ESTIMATED IMPACT OF THE PROPOSED CY 2014 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

	Number of hospitals	APC Recalibration (CY 2013–2014) (%)	Impact of packaging proposals other than outpatient laboratory services (%)	Impact of outpatient laboratory services packaging proposal (%)	APC Recalibration (all changes) (%)	New wage index and provider adjustments (%)	Combined cols 5, 6 with market basket update (%)	Column 7 with frontier wage index adjustment (%)	All proposed changes (%)
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
ALL FACILITIES *	3,953	0.0	0.0	0.0	0.0	0.0	1.8	1.9	1.8
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,791	0.1	−0.1	0.0	0.0	0.0	1.8	1.9	1.8
URBAN HOSPITALS	2,859	0.1	−0.2	0.2	0.1	0.0	1.9	2.0	2.0
LARGE URBAN (GT 1 MILL.).	1,566	0.1	0.0	0.3	0.4	0.2	2.3	2.3	2.3
OTHER URBAN (LE 1 MILL.).	1,293	0.0	−0.3	0.1	−0.2	−0.1	1.5	1.7	1.5
RURAL HOSPITALS	932	0.0	0.6	−1.3	−0.7	−0.3	0.9	1.1	0.9
SOLE COMMUNITY	389	0.1	0.8	−1.0	−0.1	−0.3	1.4	1.8	1.5
OTHER RURAL	543	0.0	0.4	−1.6	−1.2	−0.2	0.3	0.4	0.4
BEDS (URBAN)									
0–99 BEDS	959	0.0	−0.3	0.3	0.0	0.1	1.8	2.0	1.9
100–199 BEDS	831	0.1	−0.3	−0.2	−0.4	−0.1	1.3	1.4	1.4
200–299 BEDS	454	0.1	−0.6	0.1	−0.4	0.0	1.4	1.6	1.4
300–499 BEDS	407	0.3	−0.4	0.5	0.3	0.0	2.1	2.2	2.1
500 + BEDS	208	−0.1	0.6	0.2	0.7	0.2	2.6	2.6	2.6
BEDS (RURAL)									
0–49 BEDS	352	0.7	1.3	−3.5	−1.5	−0.6	−0.3	−0.1	−0.3
50–100 BEDS	342	0.2	1.5	−1.9	−0.3	−0.1	1.4	1.6	1.4
101–149 BEDS	133	−0.3	0.1	−0.6	−0.8	−0.5	0.5	0.7	0.6
150–199 BEDS	61	−0.5	0.2	−0.8	−1.1	−0.1	0.5	1.0	0.5
200 + BEDS	44	0.1	−0.6	0.3	−0.2	−0.2	1.4	1.4	1.6
VOLUME (URBAN)									
LT 5,000 Lines	485	−1.4	−0.4	2.4	0.5	0.2	2.5	2.7	2.6
5,000—10,999 Lines	109	−1.4	−0.5	3.2	1.3	−0.1	3.0	3.5	2.4
11,000–20,999 Lines	132	0.1	−1.9	2.4	0.6	0.0	2.5	2.6	2.5
21,000–42,999 Lines	262	0.4	−1.8	1.2	−0.2	−0.2	1.4	1.4	1.4
42,999—89,999 Lines	517	0.2	−0.9	0.7	−0.1	0.1	1.8	1.8	1.8
GT 89,999 Lines	1,354	0.1	0.0	0.1	0.1	0.0	2.0	2.1	2.0
VOLUME (RURAL)									
LT 5,000 Lines	31	−1.8	0.3	2.2	0.6	−0.4	2.1	6.7	2.2
5,000–10,999 Lines	34	5.8	−0.1	−4.4	1.0	−0.5	2.3	2.3	2.4
11,000–20,999 Lines	67	3.0	0.2	−2.6	0.5	−0.7	1.6	1.7	1.5
21,000–42,999 Lines	182	1.0	1.2	−2.4	−0.3	−0.3	1.2	1.8	1.1
GT 42,999 Lines	618	−0.1	0.6	−1.2	−0.7	−0.2	0.8	1.0	0.9
REGION (URBAN)									
NEW ENGLAND	150	0.0	2.2	−1.4	0.7	0.6	3.1	3.1	3.0
MIDDLE ATLANTIC	342	0.0	0.8	−0.5	0.3	0.7	2.8	2.8	2.8
SOUTH ATLANTIC	432	−0.3	−0.6	0.5	−0.4	−0.3	1.1	1.1	1.2
EAST NORTH CENT.	459	0.2	0.1	−0.3	0.0	−0.2	1.5	1.5	1.6
EAST SOUTH CENT.	172	−0.2	−0.8	0.9	−0.1	−0.3	1.4	1.4	1.5
WEST NORTH CENT.	193	0.0	0.5	1.5	2.0	−0.3	3.5	4.5	3.5
WEST SOUTH CENT.	487	0.7	−2.1	0.5	−0.9	−0.2	0.8	0.8	0.9
MOUNTAIN	194	−0.6	0.4	0.8	0.5	−0.3	2.0	2.3	2.0
PACIFIC	385	0.5	−0.9	0.6	0.2	0.6	2.6	2.6	2.5
PUERTO RICO	45	4.3	−0.5	0.0	3.9	0.6	6.3	6.3	6.6
REGION (RURAL)									
NEW ENGLAND	25	−0.3	3.5	−1.6	1.6	0.6	3.9	3.9	3.8

TABLE 39—ESTIMATED IMPACT OF THE PROPOSED CY 2014 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM—Continued

	Number of hospitals	APC Recalibration (CY 2013–2014) (%)	Impact of packaging proposals other than outpatient laboratory services (%)	Impact of outpatient laboratory services packaging proposal (%)	APC Recalibration (all changes) (%)	New wage index and provider adjustments (%)	Combined cols 5, 6 with market basket update (%)	Column 7 with frontier wage index adjustment (%)	All proposed changes (%)
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
MIDDLE ATLANTIC	68	0.3	1.7	−3.9	−2.0	−0.3	−0.4	−0.4	−0.4
SOUTH ATLANTIC	158	−0.3	−0.2	−0.9	−1.4	−0.4	0.0	0.0	0.1
EAST NORTH CENT.	124	0.0	0.8	−1.8	−1.1	−0.4	0.4	0.4	0.4
EAST SOUTH CENT.	170	0.0	−0.3	−0.8	−1.1	−0.6	0.1	0.1	0.2
WEST NORTH CENT.	99	−0.1	0.8	0.0	0.7	−0.1	2.3	3.5	2.5
WEST SOUTH CENT.	196	0.6	−0.4	−1.3	−1.1	−0.4	0.3	0.3	0.4
MOUNTAIN	63	−0.1	1.6	−1.6	−0.2	0.2	1.9	3.4	1.4
PACIFIC	29	0.2	1.9	−0.2	1.8	0.7	4.3	4.3	4.3
TEACHING STATUS									
NON-TEACHING	2,792	0.0	−0.4	−0.2	−0.6	−0.1	1.1	1.2	1.2
MINOR	686	0.0	−0.5	0.5	0.0	0.0	1.8	2.0	1.8
MAJOR	313	0.2	1.2	−0.2	1.2	0.2	3.2	3.2	3.1
DSH PATIENT PERCENT									
0	12	1.8	−5.4	3.5	−0.3	−0.1	1.5	1.5	1.4
GT 0–0.10	349	−0.4	0.2	0.6	0.4	0.1	2.3	2.4	2.3
0.10–0.16	334	−0.2	0.3	0.1	0.2	0.1	2.1	2.2	2.2
0.16–0.23	680	−0.1	0.3	−0.2	0.1	0.0	1.8	2.0	1.9
0.23–0.35	1,045	−0.2	0.1	0.1	0.0	0.0	1.7	1.9	1.8
GE 0.35	831	0.7	−0.8	−0.2	−0.3	0.0	1.5	1.5	1.5
DSH NOT AVAILABLE **	540	2.3	−1.4	1.6	2.4	0.0	4.2	4.2	3.9
URBAN TEACHING/DSH									
TEACHING & DSH	909	0.1	0.2	0.2	0.5	0.1	2.4	2.5	2.4
NO TEACHING/DSH	1,429	0.0	−0.8	0.2	−0.5	0.0	1.2	1.3	1.3
NO TEACHING/NO DSH	12	1.8	−5.4	3.5	−0.3	−0.1	1.5	1.5	1.4
DSH NOT AVAILABLE**	509	2.0	−1.2	1.5	2.3	0.1	4.2	4.2	3.9
TYPE OF OWNERSHIP									
VOLUNTARY	2,004	0.0	0.2	0.0	0.2	0.1	2.0	2.2	2.1
PROPRIETARY	1,250	0.3	−1.5	0.9	−0.4	−0.1	1.3	1.4	1.3
GOVERNMENT	537	0.3	0.1	−1.0	−0.6	−0.2	1.0	1.0	1.0
CMHCs	100	−5.4	−3.6	3.5	−5.7	−0.2	−4.1	−4.1	−3.8

Column (1) shows total hospitals and/or CMHCs.

Column (2) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups and the proposed recalibration of APC weights based on CY 2012 hospital claims data. Changes in this column do not include reconfigurations and data changes from the 2014 packaging proposal.

Column (3) shows the additional impact of changes resulting from the reclassification of HCPCS codes among APC groups and other data changes as a result of including the 2014 OPPS packaging proposal (but excluding the proposed packaging of outpatient laboratory services currently paid at CLFS rates).

Column (4) shows the additional impact of changes resulting from the reclassification of HCPCS codes among APC groups and other data changes as a result of including the 2014 OPPS proposal to package outpatient laboratory services currently paid at CLFS rates.

Column (5) includes all CY 2014 OPPS proposals and compares those to the CY 2013 OPPS (which includes outpatient laboratory services previously paid at CLFS rates).

Column (6) shows the budget neutral impact of updating the wage index by applying the FY 2014 hospital inpatient wage index. The proposed rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. Similarly, the differential in estimated cancer hospital payments for the proposed adjustment is minimal and thus results in a budget neutrality factor of 1.0001.

Column (7) shows the impact of all budget neutrality adjustments and the proposed addition of the 1.8 percent OPD fee schedule update factor (2.5 percent reduced by 0.4 percentage points for the proposed productivity adjustment and further reduced by 0.3 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (8) shows the non-budget neutral impact of applying the frontier State wage adjustment.

Column (9) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adding estimated outlier payments, and applying payment wage indexes.

* These 3,953 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs. Payments for laboratory services at CLFS rates, which we are proposing to package in the CY 2014 OPPS, are included in the columns where appropriate.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

(3) Estimated Effects of Proposed OPPS Changes on CMHCs

The last line of Table 39 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization (PHP) services under the OPPS. In CY 2013, CMHCs are paid under two APCs for these services: APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs). In contrast, hospitals are paid for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). We use our standard rate-setting methodology to derive the payment rates for each APC based on the cost data derived from claims and cost reports for the provider type to which the APC is specific. For CY 2014, we are proposing to continue the provider-specific APC structure that we adopted in CY 2011. We modeled the impact of this proposed APC policy assuming that CMHCs will continue to provide the same number of days of PHP care, with each day having either 3 services or 4 or more services, as seen in the CY 2012 claims data used for this proposed. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. Because the proposed relative payment weights for APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs) decline in CY 2014, we estimate that there would be an overall 3.8 percent decrease in payments to CMHCs (shown in Column 9).

Column 6 shows that the estimated impact of adopting the proposed FY 2014 wage index values would result in

a small decrease of 0.2 percent to CMHCs. We note that all providers paid under the OPPS, including CMHCs, would receive a 1.8 percent OPD fee schedule increase factor. Column 7 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2014 and the proposed FY 2014 wage index updates, would result in an estimated decrease of 4.1 percent. Column 8 shows that adding the proposed frontier State wage adjustment would result in no change to the cumulative 4.1 percent decrease. Column 9 shows that adding the proposed changes in outlier and pass-though payments would result in a 3.8 percent decrease in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2014.

(4) Estimated Effect of Proposed OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary share of payment would increase for services for which the OPPS payments will rise and would decrease for services for which the OPPS payments will fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this proposed rule. In all cases, the statute limits beneficiary liability for copayment for a procedure to the hospital inpatient deductible for the applicable year. The CY 2013 hospital inpatient deductible is $1,184. The amount of the CY 2014 hospital inpatient deductible is not available at the time of publication of this proposed rule.

In order to better understand the impact of proposed changes in copayment on beneficiaries, we modeled the percent change in total copayment liability using CY 2012 claims. We estimate, using the claims of the 3,791 hospitals and CMHCs on which our modeling is based, that total beneficiary liability for copayments would remain approximately the same as an overall percentage of total payments, being 20.4 percent in CY 2013 and 20.2 percent in CY 2014.

(5) Estimated Effects of Proposed OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XII. of this proposed rule. No types of providers or suppliers other than hospitals, CMHCs and ASCs would be affected by the proposed changes in this proposed rule.

(6) Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be $600 million in additional program payments for OPPS services furnished in CY 2014. The effect on the Medicaid program is expected to be limited to increased copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We refer readers to our discussion of the impact on beneficiaries in section XXIII.A. of this proposed rule.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing to make and the reasons for our selected alternatives are discussed throughout this proposed rule. In this section, we discuss some of the major issues and the alternatives considered.

• Alternatives Considered for the Establishment of Comprehensive APCs

We are proposing in section II.A.2.e. of this proposed rule to create 29 comprehensive APCs for CY 2014 to prospectively pay for device-dependent services associated with 121 HCPCS codes. We are proposing to define a comprehensive APC as a classification for the provision of a primary service and all adjunct services provided to support the delivery of the primary service. The comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, resulting in a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service as well as all adjunct services provided to support that delivery of the primary service. For these APCs, we are proposing to treat all previously individually reported codes as representing components of the comprehensive service, making a single payment for the comprehensive service based on all charges on the claim, excluding only charges for services that cannot be covered by Medicare Part B or that are not payable under the OPPS. This would create a single all-inclusive payment for the claim that is subject to a single beneficiary copayment, up to the cap set at the level of the inpatient hospital deductible.

We are proposing this as a step that we believe will further improve the accuracy of our payments for these services where there is a substantial cost for a device that is large compared to the other costs that contribute to the cost of the procedure, and where the cost of the procedure is large compared to the adjunctive and supportive services delivered along with that procedure. We also believe our proposal will enhance beneficiary understanding and transparency for the beneficiary, for physicians, and for hospitals by creating a common reference point with a similar meaning for all three groups by using the comprehensive service concept that already identifies these same services when they are performed in an inpatient environment.

In proposing to package into the comprehensive APCs all other services and supplies, we are including the diagnostic procedures, tests and treatments that assist in the delivery of the primary procedure, visits and evaluations performed in association with the procedure, uncoded services and supplies used during the service, outpatient department services delivered by therapists as part of the comprehensive service, durable medical equipment as well as the supplies to support that equipment, and any other components reported by HCPCS codes that are provided during the comprehensive service, except for mammography services and ambulance services, which are never payable as OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act.

We also considered several ranges of alternatives. First, we considered but are not proposing a limitation of the services that we considered to be ancillary and supportive to the primary service. We did not propose to limit the comprehensive APCs to only HCPCS codes that are currently paid using OPPS payment calculations because we could not identify a unique clinical characteristic that set these services apart from other services reported on the claim. We determined that services currently excluded by the Secretary from OPPS calculations, including, for example, such services as laboratory tests and certain orthotics and supplies, were adjunctive and supportive to the primary procedure in the same manner as the other services currently paid using our OPPS methodology were adjunctive and supportive. We also noted that these services that are currently priced using other payment systems represented a very small fraction of the costs reported on these device dependent claims, typically on the order of 1 percent of the total reported costs. This was consistent with our determination that these services were adjunctive and supportive and should be included in our definition of a comprehensive APC.

Second, we considered but did not propose creating comprehensive APCs

for a different cohort of device dependent procedures. We did not propose a more limited list because we determined that the 29 APCs we proposed all consistently identified truly device dependent services where the other services that are currently assigned to the other device dependent APCs that are not being proposed as comprehensive APCs were clearly provided in support of a primary procedure. We considered limiting our proposal to the five or ten procedures with the most expensive devices but believed that such a division would be arbitrary and would ignore the natural division that occurred when the costs and clinical characteristics of these services were compared to similar procedures delivered as comprehensive services to inpatients. Alternatively, we considered limiting the proposal to those comprehensive services where the procedure itself, without consideration of the device, was responsible for the most significant portion of the cost and was also responsible for the need to deliver the majority of the additional services provided during the encounter. However, although we considered that this last consideration did in fact identify services that were consistent with our proposal to define comprehensive services, we did not propose this alternative as we believe our proposal to create comprehensive APCs for only the 29 most costly device dependent APCs is most consistent with our past practices of iteratively improving the OPPS in small and well-defined increments.

Third, we considered proposing payment adjustments for instances when multiple procedures assigned to comprehensive APCs were reported on the same claim. However, we did not propose this. In examining our claims data, we determined that multiple procedures assigned to comprehensive APCs were reported in only 25 percent of the claims, and that these multiple procedures were almost always reporting components of the same service, such as cardiac stenting, and were assigned to the same APC. In our claims data it was very uncommon to find multiple unrelated device dependent procedures being delivered at the same time. Therefore, we decided to propose that the primary procedure would determine the comprehensive APC and that, in the rare event that procedures were reported that mapped to two different comprehensive APCs on the same claim, the most expensive procedure according to our traditional OPPS accounting methodology would determine the comprehensive APC assignment. We believe that this is consistent with the methodology for assigning payments for those inpatient claims that represent the same or similar comprehensive procedures and that it most accurately reflects the comprehensive service on those occasions in which two or more device dependent HCPCS codes are used to report the single comprehensive service.

Finally, we considered retaining the device-to-procedure edits and procedure-to-device edits that were characteristic of our device-dependent APCs but we instead proposed the elimination of the edits along with the elimination of the status of device dependent APC. We noted that the device-dependent APC was created in response to concerns that hospitals were not coding for the device and that our relative cost estimations were consequently incorrect. In the intervening years we have noticed a significant improvement and stabilization in the reporting of costs, to the extent that we believe that hospitals are now fully accustomed to appropriate cost reporting under the OPPS such that special billing constraints are unnecessary. We further believe that, under our proposal to create comprehensive APCs, there would now be an additional mechanism to ensure accurate cost estimation for the most expensive devices for which an inadvertent omission of costs would be most significant. In the calculations of relative cost for the comprehensive APCs, costs for the device would be correctly assigned to the procedure as long as the hospital reports covered costs anywhere on the claim. Specific device reporting would still be expected and required, but variations in accounting practices would be less likely to influence the final cost accounting.

In summary, we determined to propose to make an all-inclusive comprehensive payment for the procedures in the 29 most costly device dependent APCs because we believe that this identified a consistent set of procedures that were typically provided as a primary procedure supported by a set of adjunctive services, and that this set of services represented an incremental improvement in our prospective payments similar to other prior incremental improvements through which we have established our approach to updating and improving the OPPS.

- Alternatives Considered for Payment of Hospital Outpatient Visits

As described in section VII. of this proposed rule, we are proposing to replace the current five levels of visit codes for each clinic, Type A ED, and Type B ED visits with three new alphanumeric Level II HCPCS codes representing a single level of payment for the three types of visits, respectively. We are proposing to assign the new alphanumeric Level II HCPCS to newly created APCs with CY 2014 OPPS payment rates based on the total mean costs of Level 1 through Level 5 visit codes obtained from CY 2012 OPPS claims data for each visit type.

In developing this policy, we considered another alternative, which was to replace the current five levels of visit codes for each clinic, Type A ED, and Type B ED visit with 6 new alphanumeric Level II HCPCS codes representing two levels (lower level and higher level) of payment for each of the three types of visits. The lower-level alphanumeric codes for clinic, Type A ED, and Type B ED visits would replace the current Level 1 and Level 2 visit codes, respectively, and would be assigned to newly created or reconfigured APCs with CY 2014 OPPS payment rates based on the total mean costs of Level 1 and 2 visit codes obtained from CY 2012 OPPS claims data for each visit type. The higher-level alphanumeric codes for clinic, Type A ED, and Type B ED visits would replace the current Level 3 through Level 5 visit codes, respectively, and would be assigned to newly created or reconfigured APCs with CY 2014 OPPS payment rates based on the total mean costs of Level 3 through Level 5 visit codes obtained from CY 2012 OPPS claims data for each visit type.

While we believe that this alternative could offer advantages over the current CY 2013 OPPS visit payment policy, we did not choose this alternative because as we describe in section VII. of this proposed rule we believed that a single level of payment for each type of clinic and ED visit was the best policy option as this proposal would be easily implemented by hospitals; reduces administrative burden relative to the existing five-level visit payment structure; and maximizes hospitals' incentives to provide care in the most efficient manner as there would be no incentive to provide unnecessary care to achieve a higher level visit threshold. A two-level visit payment structure would not be as easily implemented by hospitals as a single-level visit payment structure, and the need for hospitals to develop and implement guidelines to differentiate the levels of service would continue to exist. Also, while the two-level visit payment structure may provide incentives for hospitals to be efficient, the incentives may not be so great as under a single-level visit

payment structure. Therefore, we are proposing to create three new alphanumeric Level II HCPCS codes to describe all levels of each type of clinic and ED visit rather than continue to recognize five levels each of clinic and ED visits.

b. Estimated Effects of ASC Payment System Proposed Policies

ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this proposed rule, we are proposing to set the CY 2014 ASC relative payment weights by scaling the proposed CY 2014 OPPS relative payment weights by the proposed ASC scaler of 0.8961. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 40 and 41 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which currently is the CPI–U) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2014 payment determinations will be based on the application of a 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U. We calculated the proposed CY 2014 ASC conversion factor by adjusting the CY 2013 ASC conversion factor by 1.0004 to account for changes in the pre-floor and pre-reclassified hospital wage indices between CY 2013 and CY 2014 and by applying the proposed CY 2014 MFP-adjusted CPI–U update factor of 0.9 percent (projected CPI–U update of 1.4 percent minus a projected productivity adjustment of 0.5. percent). The proposed CY 2014 ASC conversion factor is $43.321.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2014 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2012 and CY 2014 with precision. We believe that the net effect on Medicare expenditures resulting from the proposed CY 2014 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of ASC Payment System Proposed Policies on ASCs

Some ASCs are multispecialty facilities that perform the gamut of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2014 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2014 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2012 claims data. Table 40 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2013 payments to estimated CY 2014 payments, and Table 41 shows a comparison of estimated CY 2013 payments to estimated CY 2014 payments for procedures that we estimate would receive the most Medicare payment in CY 2014.

Table 40 shows the estimated effects on aggregate Medicare payments under the ASC payment system by surgical specialty or ancillary items and services group. We have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 40.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2013 ASC Payments were calculated using CY 2012 ASC utilization (the most recent full year of ASC utilization) and CY 2013 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2013 ASC payments.
- Column 3—Estimated CY 2014 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that would be attributable to proposed updates to ASC payment rates for CY 2014 compared to CY 2013.

As seen in Table 40, we estimate that the proposed update to ASC rates for CY 2014 would result in a 3 percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, an 8 percent increase in aggregate payment amounts for digestive system procedures, and a 1 percent increase in aggregate payment amounts for nervous system procedures.

Generally, for the surgical specialty groups that account for less ASC utilization and spending, we estimate that the payment effects of the proposed CY 2014 update are variable. For instance, we estimate that, in the aggregate, payment for musculoskeletal system procedures would decrease by 1 percent, whereas payment for genitourinary system procedures, integumentary system procedures and respiratory system procedures would increase by 5 to 7 percent under the proposed CY 2014 rates.

An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group would experience increased payment rates. For example, the estimated increase for CY 2014 for digestive system procedures is likely due to an increase in the ASC payment weight for some of the high volume procedures, such as CPT code 43239 (Upper GI endoscopy biopsy) where estimated payment would increase by 13 percent for CY 2014.

Also displayed in Table 40 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services would decrease by 12 percent for CY 2014.

TABLE 40—ESTIMATED IMPACT OF THE PROPOSED CY 2014 UPDATE OF THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2014 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group	Estimated CY 2013 ASC Payments (in millions)	Estimated CY 2014 percent change
(1)	(2)	(3)
Total	$3,625	1
Eye and ocular adnexa	1,496	−3
Digestive system	743	8
Nervous system	540	1
Musculoskeletal system	441	−1
Genitourinary system	159	5
Integumentary system	130	7
Respiratory system	46	7
Cardiovascular system	32	−2
Ancillary items and services	20	−12
Auditory system	12	4
Hematologic & lymphatic systems	5	17

Table 41 below shows the estimated impact of the proposed updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2014. The table displays 30 of the procedures receiving the greatest estimated CY 2014 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2014 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2013 ASC Payments were calculated using CY 2012 ASC utilization (the most recent full year of ASC utilization) and the proposed CY 2014 ASC payment rates. The estimated CY 2014 payments are expressed in millions of dollars.
- Column 4–Estimated CY 2014 Percent Change reflects the percent differences between the estimated ASC payment for CY 2013 and the estimated payment for CY 2014 based on the proposed update.

TABLE 41—ESTIMATED IMPACT OF THE PROPOSED CY 2014 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/ HCPCS code*	Short descriptor	Estimated CY 2013 ASC payments (in millions)	Estimated CY 2014 percent change
(1)	(2)	(3)	(4)
66984	Cataract surg w/iol, 1 stage	$1,107	−3
43239	Upper GI endoscopy, biopsy	163	13
45380	Colonoscopy and biopsy	154	7
45385	Lesion removal colonoscopy	98	7
66982	Cataract surgery, complex	89	−3
45378	Diagnostic colonoscopy	80	7
64483	Inj foramen epidural l/s	79	14
62311	Inject spine l/s (cd)	71	14
66821	After cataract laser surgery	59	−1
G0105	Colorectal scrn; hi risk ind	42	0
15823	Revision of upper eyelid	40	2
64493	Inj paravert f jnt l/s 1 lev	40	14
63650	Implant neuroelectrodes	39	4
G0121	Colon ca scrn not hi rsk ind	36	0
29827	Arthroscop rotator cuff repr	34	5
64590	Insrt/redo pn/gastr stimul	33	6
64721	Carpal tunnel surgery	31	−1
63685	Insrt/redo spine n generator	31	6
64636**	Destroy l/s facet jnt addl	31	−100
29881	Knee arthroscopy/surgery	30	−3
64635	Destroy lumb/sac facet jnt	26	73
29880	Knee arthroscopy/surgery	25	−3
43235	Uppr gi endoscopy diagnosis	23	13
45384	Lesion remove colonoscopy	22	7
52000	Cystoscopy	21	5
62310	Inject spine c/t	20	14

TABLE 41—ESTIMATED IMPACT OF THE PROPOSED CY 2014 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES—Continued

CPT/ HCPCS code*	Short descriptor	Estimated CY 2013 ASC payments (in millions)	Estimated CY 2014 percent change
(1)	(2)	(3)	(4)
29823	Shoulder arthroscopy/surgery	19	5
67042	Vit for macular hole	19	0
28285	Repair of hammertoe	18	5
50590	Fragmenting of kidney stone	18	2

*Note that HCPCS codes we are proposing to delete for CY 2014 are not displayed in this table.
** The 100 percent decrease in estimated payment reflects our CY 2014 proposal to package the payment for CPT code 64636.

(3) Estimated Effects of ASC Payment System Proposed Policies on Beneficiaries

We estimate that the proposed CY 2014 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are proposing to add to the ASC list of covered surgical procedures and for those that we are proposing to designate as office-based for CY 2014. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts for that service in the physician's office compared to the ASC. However, for those additional procedures that we are proposing to designate as office-based in CY 2014, the beneficiary coinsurance amount would be no greater than the beneficiary coinsurance in the physician's office because the coinsurance in both settings is 20 percent (except for certain preventive services where the coinsurance is waived in both settings).

(4) Alternative ASC Payment Policies Considered

Alternatives to the minor changes that we are proposing to make to the ASC payment system and the reasons that we have chosen specific options are discussed throughout this proposed rule. There are no proposed major changes to ASC policies for CY 2014.

c. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web site at: *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf),* we have prepared two accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 42 (below) illustrates the classification of expenditures for the CY 2014 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2014 OPD fee schedule increase, based on the 2013 Trustee's Report. The second accounting statement, Table 43 (below) illustrates the classification of expenditures associated with the proposed 0.9 percent CY 2014 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the 2013 Trustee's Report. The third accounting statement, Table 44 (below), illustrates the classification of expenditures associated with the proposed revision to the definition of hospital-based EP in payment year 2013 for EPs reassigning benefits to Method II CAHs. Lastly, the tables classify most estimated impacts as transfers.

TABLE 42—ACCOUNTING STATEMENT: CY 2014 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2013 TO CY 2014 ASSOCIATED WITH THE PROPOSED CY 2014 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$600 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS.
Total	$600 million.

TABLE 43—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2013 TO CY 2014 AS A RESULT OF THE PROPOSED CY 2014 UPDATE TO THE REVISED ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$27 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.

TABLE 43—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2013 TO CY 2014 AS A RESULT OF THE PROPOSED CY 2014 UPDATE TO THE REVISED ASC PAYMENT SYSTEM—Continued

Category	Transfers
Total	$27 million.

TABLE 44—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2013 TO CY 2014 AS A RESULT OF THE PROPOSED REVISIONS TO THE DEFINITION OF PROVIDER–BASED EP UNDER THE EHR INCENTIVE PROGRAM

Category	Transfers
Annualized Monetized Transfers	$17,985,000 to $35,970,000.
From Whom to Whom	Federal Government to Medicare Providers.
Total	$17,985,000 to $35,970,000.

d. Effects of Proposed Requirements for the Hospital OQR Program

In section XIII. of this proposed rule, we are proposing to adopt policies affecting the Hospital OQR Program.

We determined that 114 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor for CY 2013. Most of these hospitals (106 of the 114) received little or no OPPS payment on an annual basis and did not participate in the Hospital OQR Program. We estimate that 106 hospitals may not receive the full OPD fee schedule increase factor in CY 2014 and that 106 hospitals may not receive the full OPD fee schedule increase factor in CY 2015. We are unable at this time to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2016.

In section XVI.E.3.a. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60647 through 60650), for the CY 2011 payment update, as part of the validation process, we required hospitals to submit paper copies of requested medical records to a designated contractor within the required timeframe. Failure to submit requested documentation could result in a 2.0 percentage point reduction to a hospital's CY 2011 OPD fee schedule increase factor, but the failure to attain a validation score threshold would not.

In section XVI.D.3.b of the CY 2011 OPPS/ASC final rule with comment period, we finalized our proposal to validate data submitted by 800 hospitals of the approximately 3,200 participating hospitals for purposes of the CY 2012 Hospital OQR Program payment determination. We stated our belief that this approach was suitable for the CY 2012 Hospital OQR Program because it would: produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; provide more statistically reliable estimates of the quality of care delivered in each selected hospital as well as at the national level; and reduce overall hospital burden because most hospitals would not be selected to undergo validation each year. We adopted a threshold of 75 percent as the threshold for the validation score because we believed this level was reasonable for hospitals to achieve while still ensuring accuracy of the data. Additionally, this level is consistent with what we adopted in the Hospital IQR Program (75 FR 50225 through 50229). As a result, we believed that the effect of our validation process for CY 2012 would be minimal in terms of the number of hospitals that would not meet all program requirements.

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to validate data submitted by up to 500 of the approximately 3,200 participating hospitals for purposes of the CY 2013 Hospital OQR Program payment determination. Under our policy for CY 2011, CY 2012, and CY 2013, we stated that we would conduct a measure level validation by assessing whether the measure data submitted by the hospital matches the independently reabstracted measure data.

In the CY 2013 OPPS/ASC final rule with comment period, for the CY 2014 payment determination and subsequent years, we made some modifications to administrative requirements in extending a deadline to submit a Notice of Participation as well as to extraordinary circumstance waiver or extension and reconsideration processes to broaden the scope of personnel who can sign these requests. However, we did not make any modifications to our validation requirements. We expect these policies to have minimal impact on the program.

In this proposed rule, for CY 2016 payment determination and subsequent years, we are proposing to add five quality measures with data collection to begin in CY 2014. For four of these measures, data would be submitted via an online tool located on a CMS Web site and one would be submitted via CDC's NHSN. We are proposing to remove two measures from the Hospital OQR Program.

As stated above, we are unable to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2016. We also are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the CY 2016 payment update.

The validation requirements for CY 2014 would result in medical record documentation for approximately 6,000 cases per quarter for CY 2014, being submitted to a designated CMS contractor. We will pay for the cost of sending this medical record documentation to the designated CMS contractor at the rate of 12 cents per page for copying and approximately $1.00 per case for postage. We have found that an outpatient medical chart is generally up to 10 pages. Thus, as a result of validation requirements effective for CY 2014, we estimate that we will have expenditures of approximately $13,200 per quarter for CY 2014. Because we will pay for the data collection effort, we believe that a requirement for medical record documentation for 6,000 total cases per quarter for up to 500 hospitals for CY 2014 represents a minimal burden to Hospital OQR Program participating hospitals.

e. Effects of Proposals for the ASCQR Program

In section XV. of this proposed rule, for the ASCQR Program, we are proposing four additional quality

measures for the CY 2016 payment determination and subsequent years. Data collection for these proposed measures would begin in CY 2014. We are proposing to collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these four proposed chart-abstracted measures via an online Web-based tool located on a CMS Web page. We are also proposing for the CY 2016 payment determination and subsequent years requirements for facility participation, data collection, and submission for claims-based, CMS Web-based, and NHSN measures.

We are unable at this time to estimate the number of ASCs that may not receive the full ASC annual payment update in CYs 2014, 2015, and 2016. However, we do expect our new policies to significantly affect the number of ASCs that do not receive a full annual payment update in CY 2016, though we are not able to estimate the level of this impact at this time.

f. Effects of Proposed Changes to the CfCs for OPOs Relating to the Outcome Measures Requirement for Recertification

In section XVI. of this proposed rule, we discussed our proposal to modify the current outcome measures requirement that OPOs meet all three outcome measures set forth in § 486.318 to a requirement that they meet two out of the three outcome measures. Our proposal would result in those OPOs that fail only one outcome measures avoiding automatic decertification based upon the current outcome measures requirement.

While we are confident that our proposal would have a significantly positive effect on the OPOs that avoided automatic decertification, it is very difficult to quantify the impact of this change. As discussed under section XXI.C. of this proposed rule relating to the ICR requirements, we anticipate that most OPOs that are decertified would engage in the appeals process as set forth in § 486.314. However, we have no reliable way of estimating how many OPOs would likely obtain reversals of their decertifications during reconsideration or how many continue on to a hearing before a CMS hearing officer. Therefore, although we believe there would be a considerably large positive effect as a result of our proposed change to the outcome measures requirement, we are unable to provide a specific estimate of that cost savings.

g. Effects of Proposed Revisions of the QIO Regulations

In section XVII. of this proposed rule, we are proposing to update the regulations at 42 CFR parts 475 and 476 based on the recently enacted Trade Adjustment Assistance Extension Act of 2011 (TAAEA) (Pub. L. 112–40, Section 261) whereby Congress authorized numerous changes to the original legislation and included additional flexibility for the Secretary in the administration of the QIO program. Currently, 42 CFR Part 475 includes definitions and standards governing eligibility and the award of contracts to QIOs. In this proposed rule, we set forth proposals for the partial deletion and revision of the regulations under 42 CFR Parts 475 and 476, which relate to the QIO program, including the following: (1) Replace nomenclature that has been amended by the TAAEA; (2) revise the existing definition for the term ''physician'' in Parts 475 and 476; (3) add new definitions as necessary to support the new substantive provisions in Subpart C; and (4) revise, add, and replace some of the substantive provisions in Subpart C to fully exercise the Secretary's authority for the program and update the contracting requirements to align with contemporary quality improvement.

We estimate the effects of the proposed QIO Program changes to be consistent with the Congressional Budget Office's 2011 Cost Estimate of the Trade Bill (H.R. 2832) which included a reduction in spending of $330 million over the 2012–2021 period. According to the CBO Estimate, the Act and subsequently the proposed regulatory changes ''would modify the provisions under which CMS contracts with independent entities called ['']Quality Improvement Organizations [(QIOs)''] in Medicare. QIOs, generally staffed by health care professionals, review medical care, help beneficiaries with complaints about the quality of care, and implement care improvements. H.R. 2832 would make several changes to the composition and operation of QIOs, and would harmonize QIO contracts with requirements of the Federal Acquisition Regulation. Among those changes are a modification to expand the geographic scope of QIO contracts and a lengthening of the contract period. CBO estimates that those provisions would reduce spending by $330 million over the 2012–2021 period.''

h. Effects of Proposals Regarding Medicare-Fee-for-Service EHR Incentive Program

(1) Incentive Payments for Eligible Professionals (EPs) Reassigning Benefits to Method II CAHs

As discussed in section XVIII.A. of this proposed rule, we are proposing to revise the regulations to provide, during payment year 2013 alone, a special method for determining the hospital-based status of EPs who reassign their benefits to Method II CAHs. It is difficult to determine with precision the cost impact of this proposal. We lack specific information on key factors affecting this impact, including the number of EPs who reassign their benefits to Method II CAHs, the proportion of those EPs who would be determined to be nonhospital-based for 2013 under our proposal, the proportion of those EPs who will qualify for Medicaid incentive payments and choose to accept those payments because they are higher, and the proportion of the remaining EPs who will successfully demonstrate meaningful use in order to qualify for Medicare incentive payments. It is therefore necessary to rely on estimates for each of these factors. As much as possible we will employ the methods of cost estimation that we used to determine the estimated costs of the Medicare incentives for EPs in our Stage 1 final rule (75 FR 44549) and Stage 2 final rule (77 FR 54139) for the Medicare Electronic Health Record Incentive Program, as well as the estimates that we have previously employed for specific factors.

Of the approximately 1,200 CAHs, about three-quarters, or 900, elect under section 1834(g)(2) of the Act to receive a cost-based payment for the facility costs of providing outpatient services, plus 115 percent of the fee schedule amount for professional services included within outpatient CAH services. As we have indicated, we lack specific information on the numbers of EPs who reassign their benefits to these Method II CAHs. While CAHs are relatively small inpatient facilities, we understand that many of them have fairly substantial outpatient clinics. At the same time, we have also been informed that they rely largely on nonphysician practitioners (nurses and nurse practitioners) to staff these outpatient clinics. Therefore, we will assume that the typical outpatient department in a Method II CAH has a relatively small number of physicians, between 5 and 10, on staff and billing for professional services that are reassigned to the CAH. We will also use

this estimate of 5 to 10 physicians per Method II CAH to establish an upper and lower range to our impact estimate. The number of EPs reassigning benefits for outpatient services to Method II CAHs is therefore between 4,500 and 9,000.

In our Stage 2 final rule (77 FR 54139) for the Medicare Electronic Health Record Incentive Program, we determined that about 14 percent of EPs with Medicare claims were hospital-based, and thus ineligible to receive Medicare EHR incentive payments. For purposes of this impact statement, we will assume that 10 percent of EPs reassigning benefits to Method II CAHs are hospital-based. Because CAHs have relatively small inpatient hospital facilities, we believe that the physicians practicing in these facilities will bill for somewhat fewer inpatient services than EPs generally. Using this assumption, the estimate of nonhospital-based EPs reassigning benefits to Method II CAHs is therefore between 4,050 and 8,100. Of these nonhospital-based EPs reassigning benefits to Method II CAHs, some proportion will qualify for Medicaid incentive payments and will choose to receive payments under that program because the payments are higher. For these purposes we will employ the same estimate (20 percent) that we have employed for developing cost estimate in our Stage 2 final rule (77 FR 54140). Thus, we estimate that between 3,240 and 6,480 non-hospital-based EPs reassigning benefits to Method II CAHs do not choose to receive Medicaid incentive payments.

As we have discussed in prior rules (77 FR 54140) our estimates for the number of EPs that will successfully demonstrate meaningful use of CEHRT are uncertain. The percentage of Medicare EPs who will satisfy the criteria for demonstrating meaningful use of CEHRT and will qualify for incentive payments is a key, but highly uncertain factor in developing cost estimates for the EHR incentive program in general and for the present purposes in particular. Consistent with the estimates that we have employed for EPs generally in developing cost estimates in the Stage II final rule, we will assume that 37 percent of the nonhospital-based EPs reassigning benefits to Method II CAHs will satisfy the criteria for demonstrating meaningful use of CEHRT and will qualify for incentive payments in payment years 2013. Thus, we estimate that between 1,199 and 2,398 EPs reassigning benefits to Method II CAHs will actually qualify to receive Medicare EHR incentive payments in 2013. As we have previously discussed, section 1848(o)(1)(B) of the Act provides that the incentive payment for an EP for a given payment year shall not exceed the following amounts:

- For the EP's first payment year, for such professional, $15,000 (or $18,000, if the EP's first payment year is 2011 or 2012);
- For the EP's second payment year, $12,000;
- For the EP's third payment year, $8,000;
- For the EP's fourth payment year, $4,000;
- For the EP's fifth payment year, $2,000; and
- For any succeeding year, $0.

We lack any information on how many of the EPs reassigning benefits to Method II CAHs will qualify for incentive payments for the first time in 2013. However, if we assume for purposes of setting upper limits on our estimates, that all of the 1,199 to 2,398 EPs we have estimated will receive qualify for the first time and receive the maximum incentive payment, our proposal will cost between $17,985,000 and $35,970,000 in payments that we have not previously been making in 2013. Despite the uncertainties of the assumptions that we have employed in developing these estimates, we can state with reasonable confidence that our proposal will result in considerably less than $50,000,000 in payments over and above the payments we would make in the absence of this proposal for 2013.

(2) Cost Reporting Periods for Interim and Final EHR Incentive Payments to Eligible Hospitals

As we discussed in section XVIII.B. of this proposed rule, we are proposing to revise the regulations to provide that, in cases where there is no 12-month cost reporting period that begins on or after the beginning of a payment year, we will use the most recent 12-month cost reporting period available at the time of final settlement in order to determine final EHR incentive payments for the hospital. We are making this proposal solely to address situations in which hospitals have been receiving interim EHR payments but the contractors have not been able to make a determination of final payments because there is no hospital cost report that meets the existing requirements of the regulations. Therefore, we do not expect this to have any financial impact. This proposal would merely allow us to make final settlements in cases that the current regulations do not cover.

B. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $35.5 million or less in any single year. Most ASCs and most CMHCs are considered small businesses with total revenues of $10 million or less in any single year. We estimate that this proposed rule may have a significant impact on approximately 2,004 hospitals with voluntary ownership. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards.*

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule may have a significant impact on approximately 694 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $141 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and will affect both CMHCs and

ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2013. Table 39 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.8 percent increase in payments for all services paid under the OPPS in CY 2014, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed wage index changes, including the proposed frontier State wage index adjustment, estimated payment for outliers, and proposed changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains and others would experience modest losses in OPPS payments in CY 2014. We estimate that rural hospitals with 100 or fewer beds would experience a decrease of 3.9 percent. CMHCs would see an overall decrease in payment of 7.7 percent as a result of a decrease in their estimated costs. However, urban hospitals in Puerto Rico would experience an estimated 7.9 percent increase in payment, and non-teaching hospitals for whom DSH data are not available (non-IPPS hospitals) would experience a 5.3 percent increase in payment.

The proposed updates to the ASC payment system for CY 2014 would affect each of the approximately 5,300 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are proposed to be changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 40 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted CPI–U update factor of 0.9 percent for CY 2014.

XXIIV. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 39 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 0.5 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 475

Grant programs-health, Health care, Health professions, Quality Improvement Organization (QIO)

42 CFR Part 476

Health care, Health professional, Health record, Quality Improvement Organization (QIO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 495

Computer technology, Electronic health records, Electronic transactions, Health, Health care. Health information technology, Health insurance, Health records, Hospitals, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405, Subpart R continues to read as follows:

Authority: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

■ 2. Section 405.1804 is amended by revising paragraph (a) to read as follows:

§ 405.1804 Matters not subject to administrative and judicial review under prospective payment system.

* * * * *

(a) The determination of the requirement, or the proportional amount, of the budget neutrality adjustment in the prospective payment rates required under section 1886(e)(1) of the Social Security Act.

* * * * *

■ 3. Section 405.1885 is amended by revising paragraph (a)(1) and adding paragraph (b)(2)(iv) to read as follows:

§ 405.1885 Reopening an intermediary determination or reviewing entity decision.

(a) * * *

(1) A Secretary determination, an intermediary determination, or a decision by a reviewing entity (as described in § 405.1801(a)) may be reopened, with respect to specific findings on matters at issue in a determination or decision, by CMS (with respect to Secretary determinations), by the intermediary (with respect to intermediary determinations), or by the reviewing entity that made the decision (as described in paragraph (c) of this section).

(i) A specific finding on a matter at issue may be legal or factual in nature or a mixed matter of both law and fact.

(ii) A specific finding on a matter at issue may include a factual matter that arose in or was determined for the same cost reporting period as the period at issue in an appeal filed, or a reopening requested by a provider or initiated by an intermediary, under this subpart.

(iii) A specific finding on a matter at issue may include a predicate fact, which is a factual matter that arose in or was determined for a cost reporting period that predates the period at issue (in an appeal filed, or a reopening requested by a provider or initiated by an intermediary, under this subpart), and such factual matter was used in determining an aspect of the provider's reimbursement for a later cost reporting period.

(iv) A specific finding on a matter at issue may not be reopened, and if reopened, revised, except as provided for by this section, § 405.1887, and § 405.1889.

* * * * *

(b) * * *

(2) * * *

(iv) The 3-year period described in paragraphs (b)(2)(i) through (b)(2)(iii) of this section applies to, and is calculated separately for, each specific finding on a matter at issue (as described in paragraphs (a)(1)(i) through (iv) of this section.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 4. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. Section 410.27 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. Removing the word ''and'' at the end of paragraph (a)(1)(iii).

■ c. Removing the period at the end of paragraph (a)(1)(iv)(E) and adding in its place ''; and''.

■ d. Adding paragraph (a)(1)(v).

The revisions and addition read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered, if—

(1) * * *

(v) In accordance with applicable State law.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 6. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and sec. 124 of Public Law 106–113 (113 Stat. 1501A–332).

■ 7. Section 412.167 is amended by redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c) to read as follows:

§ 412.167 Appeals under the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

(c) If a hospital is dissatisfied with CMS' decision on an appeal request submitted under paragraph (b) of this section, the hospital may request an independent CMS review of that decision.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 8. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and1395hh).

■ 9. Section 416.171 is amended by revising paragraph (b)(2) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(2) Device-intensive procedures assigned to any APC under the OPPS with device costs greater than 50 percent of the APC costs based on the standard OPPS APC ratesetting methodology.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 10. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395(t), and 1395hh).

■ 11. Section 419.2 is amended by revising paragraphs (b) introductory text, (b)(3), (b)(4), (b)(7), (b)(11), and (b)(12) and adding paragraphs (b)(13) through (17) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) *Determination of hospital outpatient prospective payment rates: Packaged costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are integral, ancillary, supportive, dependent, or adjunctive to performing a procedure or furnishing a service on an outpatient basis. In general, these packaged costs may include, but are not limited to, the following items and services, the payment for which are packaged or conditionally packaged into the payment for the related procedures or services.

* * * * *

(3) Observation services;

(4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies (including, for example, but not limited to, implantable or certain nonimplantable medical devices, certain drugs and biologicals, implantable biologicals, and skin substitutes or similar wound treatment products) and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;

* * * * *

(7) Ancillary services;

* * * * *

(11) Implantable and insertable medical items and devices, including, but not limited to, prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices;

(12) Costs incurred to procure donor tissue other than corneal tissue;

(13) Image guidance, processing, supervision, and interpretation services;

(14) Intraoperative items and services;

(15) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents;

(16) Certain clinical diagnostic laboratory tests; and

(17) Procedures described by add-on codes.

* * * * *

■ 12. Section 419.22 is amended by revising the introductory text and paragraphs (j) and (l) to read as follows:

§ 419.22 Hospital outpatient services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system (except when packaged as a part of a bundled payment):

* * * * *

(j) Except as provided in § 419.2(b)(4) and (11), prosthetic devices,-prosthetic supplies, and orthotic devices.

* * * * *

(l) Except as provided in § 419.2(b)(16), clinical diagnostic laboratory tests.

* * * * *

■ 13. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*5*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*5*) For calendar year 2014, a multifactor productivity adjustment (as determined by CMS) and 0.3 percentage point.

* * * * *

■ 14. Section 419.46 is added to Subpart D to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) *Participation in the Hospital OQR Program.* To participate in the Hospital OQR Program, a hospital as defined in section 1886(d)(1)(B) of the Act and is paid under the OPPS must—

(1) Register on the QualityNet Web site before beginning to report data;

(2) Identify and register a QualityNet security administrator as part of the registration process under paragraph (a)(1) of this section; and

(3) Complete and submit an online participation form available at the QualityNet.org Web site if this form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN). For Hospital OQR Program purposes, hospitals that share the same CCN are required to complete a single online participation form. Once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant until such time as it submits a withdrawal form to CMS or no longer has an effective Medicare provider agreement. Deadlines for the participation form are described in paragraphs (a)(3)(i) and (ii) of this section, and are based on the date identified as a hospital's Medicare acceptance date.

(i) If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must complete and submit to CMS a completed Hospital OQR Notice of Participation Form by July 31 of the calendar year prior to the affected annual payment update.

(ii) If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date.

(b) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital may withdraw any time from January 1 to November 1 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.43(h), and is required to submit a new participation form in order to participate in any future year of the Hospital OQR Program.

(c) *Submission of Hospital OQR Program data*—(1) *General rule.* Except as provided in paragraph (d) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(17)(C) of the Act in a form and manner, and at a time, specified by CMS.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the QualityNet Web site.

(3) *Initial submission deadlines for a hospital that did not participate in the previous year's Hospital OQR Program.* (i) If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update, in addition to submitting a completed Hospital OQR Notice of Participation Form under paragraph (a)(3)(i) of this section.

(ii) If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit data for encounters beginning with the first full quarter following submission of the completed Hospital OQR Notice of Participation Form under paragraph (a)(3)(ii) of this section.

(iii) Hospitals with a Medicare acceptance date before or after January 1 of the year prior to an affected annual payment update must follow data submission deadlines as specified in paragraph (c)(2) of this section.

(d) *Exception.* CMS may grant an extension or waiver of one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an extension or waiver as follows:

(1) Upon request by the hospital. Specific requirements for submission of a request for an extension or waiver are available on the QualityNet Web site.

(2) At the discretion of CMS. CMS may grant waivers or extensions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(e) *Validation of Hospital OQR Program data.* CMS may validate one or more measures selected under section 1833(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request.

(2) A hospital meets the validation requirement with respect to a fiscal year if it achieves at least a 75-percent reliability score, as determined by CMS.

(f) *Reconsiderations and appeals of Hospital OQR Program decisions.* (1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital

OQR Program for a particular fiscal year. Except as provided in paragraph (d) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet Web site, no later than the first business day of the month of February of the affected payment year.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) The CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital;

(iv) The hospital's basis for requesting reconsideration. The hospital must identify its specific reason(s) for believing it should not be subject to the reduced annual payment update;

(v) The hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box);

(vi) The hospital-designated personnel's signature;

(vii) A copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and

(viii) If the hospital is requesting reconsideration on the basis that CMS determined it did not meet the affected payment determination year's validation requirement set forth in paragraph (e)(1) of this section, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered.

(3) A hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R, of this chapter.

■ 15. Section 419.66 is amended by revising paragraph (b)(3) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(b) * * *

(3) The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, whether or not is remains with the patient when the patient is released from the hospital.

* * * * *

PART 475—QUALITY IMPROVEMENT ORGANIZATIONS

■ 16. The authority citation for part 475 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 17. Section 475.1 is amended by—

■ a. Redesignating paragraphs (a) through (d) in the definition of ''Five percent or more owner'' as paragraphs (1) through (4).

■ b. Adding, in alphabetical order, the definitions of ''Case reviews'', ''Practitioner'', ''QIO area'', and Quality improvement initiative''.

■ c. Revising the definition of ''Physician''.

The additions and revision read as follows:

§ 475.1 Definitions.

* * * * *

Case reviews means the different types of reviews that QIOs are authorized to perform. Such reviews include, but are not limited to—

(1) Beneficiary complaint reviews;

(2) General quality of care reviews;

(3) Emergency Medical Treatment and Labor Act (EMTALA) reviews;

(4) Medical necessity reviews, including appeals and DRG validation reviews; and

(5) Admission and discharge reviews.

* * * * *

Physician means:

(1) A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor as described in section 1861(r) of the Act;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) of this definition; and

(3) An individual licensed to practice as a doctor as described in paragraph (1) of this definition in any Territory or Commonwealth of the United States of America.

Practitioner has the same meaning as provided in § 476.1 of this chapter.

QIO area means the defined geographic area, such as the State(s), region(s), or community(ies), in which the CMS contract directs the QIO to perform.

Quality improvement initiative has the same meaning as provided in § 476.1 of this chapter.

■ 18. Subpart C is revised to read as follows:

Subpart C—Quality Improvement Organizations

Sec.

Subpart C—Quality Improvement Organizations

§ 475.100 Scope and applicability.

This subpart implements sections 1152 and 1153(b) and (c) of the Social Security Act as amended by section 261 of the Trade Adjustment Assistance Extension Act of 2011. This subpart defines the types of organizations that are eligible to become Quality Improvement Organizations (QIOs) and describes certain steps CMS will take in selecting QIOs.

§ 475.101 Eligibility requirements for QIO contracts.

In order to be eligible for a QIO contract, an organization must meet the following requirements:

(a) Have a governing body that includes at least one individual who is a representative of health care providers and at least one individual who is a representative of consumers.

(b) Demonstrate the ability to perform the functions of a QIO, including—

(1) The ability to meet the eligibility requirements and perform activities as set forth in the QIO Request for Proposal; and

(2) The ability to—

(i) Perform case reviews as described in § 475.102; and/or

(ii) Perform quality improvement initiatives as set forth in § 475.103.

(c) Demonstrate the ability to actively engage beneficiaries, families, and consumers, as applicable, in case reviews as set forth in § 475.102, or quality improvement initiatives as set forth in § 475.103.

§ 475.102 Requirements for performing case reviews.

(a) In determining whether or not an organization has demonstrated the ability to perform case review, CMS will take into consideration factors such as:

(1) The organization's proposed processes, capabilities, quantitative, and/or qualitative performance objectives and methodology to perform case reviews;

(2) The organization's proposed involvement of and access to physicians and practitioners in the QIO area with

the appropriate expertise and specialization in the areas of health care related to case reviews;

(3) The organization's ability to take into consideration urban versus rural, and regional characteristics in the health care setting where the care under review was provided;

(4) The organization's ability to take into consideration evidence-based national clinical guidelines and professionally recognized standards of care; and

(5) The organization's access to qualified information technology (IT) expertise.

(b) In making determinations under this section, CMS may consider characteristics such as the organization's geographic location and size. CMS may also consider prior experience in health care quality improvement that CMS considers relevant to performing case reviews; such prior experience may include prior similar case review experience.

(c) A State government that administers a Medicaid program will be considered incapable of performing case review in an effective manner, unless the State demonstrates to the satisfaction of CMS that the State agency performing the case review will act with complete objectivity and independence from the Medicaid program.

§ 475.103 Requirements for performing quality improvement initiatives.

(a) In determining whether or not an organization has demonstrated the ability to perform quality improvement initiatives, CMS will take into consideration factors such as:

(1) The organization's proposed processes, capabilities, quantitative, and/or qualitative performance objectives, and methodology to perform quality improvement initiatives;

(2) The organization's proposed involvement of and access to physicians and practitioners in the QIO area that have the requisite expertise and specialization in the areas of health care concerning the quality improvement initiative; and

(3) The organization's access to professionals with requisite knowledge of quality improvement methodologies and practices, as well as qualified information technology and technical expertise.

(b) In making determinations under this section, CMS may consider characteristics such as the organization's geographic location and size. CMS may also consider prior experience in health care quality improvement that CMS considers relevant to performing quality improvement initiatives; such prior experience may include prior similar quality improvement initiative experience.

(c) A State government that administers a Medicaid program will be considered incapable of performing quality improvement initiative functions in an effective manner, unless the State demonstrates to the satisfaction of CMS that the State agency performing the quality improvement initiatives will act with complete objectivity and independence from the Medicaid program.

§ 475.104 [Reserved]

§ 475.105 Prohibition against contracting with health care facilities, affiliates, and payor organizations.

(a) *Basic rule.* Except as permitted under paragraph (a)(3) of this section, the following are not eligible for QIO contracts:

(1) A health care facility in the QIO area.

(2) A health care facility affiliate; that is, an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility in the QIO area.

(3) A payor organization, unless the Secretary determines that there is no other entity available for an area with which the Secretary can enter into a contract under this part or the Secretary determines that a payor organization is a more qualified entity to perform one or more of the functions of a QIO described in § 475.101(b) and this more qualified entity meets all other requirements and standards of this part.

(b) [Reserved]

(c) *Subcontracting.* A QIO must not subcontract with a health care facility to perform any case review activities except for the review of the quality of care.

§ 475.106 [Reserved]

§ 475.107 QIO contract awards.

Subject to the provisions of § 475.105, CMS will take the following actions in awarding QIO contracts:

(a) Identify, from among all proposals submitted in response to a Request for Proposal, all proposals submitted by organizations that meet the requirements of § 475.101;

(b) Identify, from among all proposals identified in paragraph (a) of this section, all proposals that set forth minimally acceptable plans in accordance with the requirements of § 475.102 or § 475.103, as applicable; and

(c) Award the contract to the selected organization for a specific QIO area for a period of 5 years.

PART 476—QUALITY IMPROVEMENT ORGANIZATION REVIEW

■ 19. The authority for part 476 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 20. The heading of part 476 is revised to read as set forth above.

■ 21. In § 461.1, paragraphs (a) through (d) in the definition of ''Five percent or more owner'' are redesignated as paragraphs (1) though (4) and the definition of ''Physician'' is revised to read as follows:

§ 476.1 Definitions.

* * * * *

Physician means:

(1) A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor, as described in section 1861(r) of the Act;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) of this definition; and

(3) An individual licensed to practice as a doctor as described in paragraph (1) of this definition in any Territory or Commonwealth of the United States of America.

■ 22. The heading of Subpart C is revised to read as follows:

Subpart C—Review Responsibilities of Quality Improvement Organizations (QIOs)

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 23. The authority citation of part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1302b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 24. Section 486.316 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 486.316 Re-certification and competition processes.

(a) * * *

(1) Meets two out of the three outcome measures requirements at § 486.318; and * * *

(b) *Decertification and competition.* If an OPO does not meet two out of the

three outcome measures as described in paragraph (a)(1) of this section or the requirements described in paragraph (a)(2) of this section, the OPO is decertified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the decertification, the OPO's service area is opened for competition from other OPOs. The decertified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

* * * * *

■ 25. Section 486.318 is amended by revising paragraph (a) introductory text and paragraph (b) introductory text to read as follows:

§ 486.318 Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions, an OPO must meet two out of the three following outcome measures:

* * * * *

(b) For OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions, an OPO must meet two out of the three following outcome measures:

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 26. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 27. Section 495.4 is amended by revising the definition of ''Hospital-based EP'' to read as follows:

§ 495.4 Definitions.

* * * * *

Hospital-based EP. Unless it meets the requirements of § 495.5, a hospital-based EP means an EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the payment year, or in the case of a payment adjustment year, in either of the 2 years before the year preceding such payment adjustment year.

(1) For Medicare, this is calculated based on—

(i) The Federal fiscal year preceding the payment year; and

(ii) For the payment adjustments, based on—

(A) The Federal fiscal year 2 years before the payment adjustment year; or

(B) The Federal fiscal year 3 years before the payment adjustment year.

(2) For Medicaid, it is at the State's discretion if the data are gathered on the Federal fiscal year or calendar year preceding the payment year.

(3) For the CY 2013 payment year only, an EP who furnishes services billed by a CAH receiving payment under Method II (as described in § 413.70(b)(3) of this chapter) is considered to be hospital-based if 90 percent or more of his or her covered professional services are furnished in sites of service identified by the codes used in the HIPPA standard transaction as an inpatient hospital or emergency room setting in each of the Federal fiscal years 2012 and 2013.

* * * * *

■ 28. Section 495.104 is amended by revising paragraph (c)(2) to read as follows:

§ 495.104 Incentive payments to eligible hospitals.

* * * * *

(c) * * *

(2) *Interim and final payments.* CMS uses data on hospital acute care inpatient discharges, Medicare Part A acute care inpatient bed-days, Medicare Part C acute care inpatient bed-days, and total acute care inpatient bed-days from the latest submitted 12-month hospital cost report as the basis for making preliminary incentive payments. Final payments are determined at the time of settling the first 12-month hospital cost report for the hospital fiscal year that begins on or after the first day of the payment year, and settled on the basis of data from that cost reporting period. In cases where there is no 12-month hospital cost report period beginning on or after the first day of the payment year, final payments may be determined and settled on the basis of data from the most recently submitted 12-month hospital cost report.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778 (Medical Assistance)

Dated: June 18, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 26, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–16555 Filed 7–8–13; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 78 Friday,
No. 139 July 19, 2013

Part IV

Department of Housing and Urban Development

24 CFR Parts 5, 91, 92, et al.
Affirmatively Furthering Fair Housing; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 91, 92, 570, 574, 576, and 903

[Docket No. FR–5173–P–01]

RIN No. 2501–AD33

Affirmatively Furthering Fair Housing

AGENCY: Office of the Secretary, HUD.

ACTION: Proposed rule.

SUMMARY: Through this rule, HUD proposes to provide HUD program participants with more effective means to affirmatively further the purposes and policies of the Fair Housing Act, which is Title VIII of the Civil Rights Act of 1968. The Fair Housing Act not only prohibits discrimination but, in conjunction with other statutes, directs HUD's program participants to take steps proactively to overcome historic patterns of segregation, promote fair housing choice, and foster inclusive communities for all. As acknowledged by the U.S. Government Accountability Office (GAO) and many stakeholders, advocates, and program participants, the current practice of affirmatively furthering fair housing carried out by HUD grantees, which involves an analysis of impediments to fair housing choice and a certification that the grantee will affirmatively further fair housing, has not been as effective as had been envisioned. This rule accordingly proposes to refine existing requirements with a fair housing assessment and planning process that will better aid HUD program participants fulfill this statutory obligation and address specific comments the GAO raised. To facilitate this new approach, HUD will provide states, local governments, insular areas, and public housing agencies (PHAs), as well as the communities they serve, with data on patterns of integration and segregation; racially and ethnically concentrated areas of poverty; access to education, employment, low-poverty, transportation, and environmental health, among other critical assets; disproportionate housing needs based on the classes protected under the Fair Housing Act; data on individuals with disabilities and families with children; and discrimination. From these data, program participants will evaluate their present environment to assess fair housing issues, identify the primary determinants that account for those issues, and set forth fair housing priorities and goals. The benefit of this approach is that these priorities and goals will then better inform program participant's strategies and actions by improving the integration of the assessment of fair housing through enhanced coordination with current planning exercises. This proposed rule further commits HUD to greater engagement and better guidance for program participants in fulfilling their obligation to affirmatively further fair housing. With this new clarity through guidance, a template for the assessment, and a HUD-review process, program participants should achieve more meaningful outcomes that affirmatively further fair housing.

DATES: Comment Due Date: September 17, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500: Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0001.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov*. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the toll-free Federal Relay Service during working hours at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Camille Acevedo, Associate General Counsel for Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10282, Washington, DC 20410; telephone number 202–708–1793 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Relay Service during working hours at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

Purpose of the Regulatory Action

From its inception, the Fair Housing Act (and subsequent laws reaffirming its principles) outlawed discrimination and set out steps that needed to be taken proactively to overcome the legacy of segregation through the obligation of affirmatively furthering fair housing (AFFH).

Informed by lessons learned in localities across the country, HUD issues this proposed rule, which provides new tools now available to help guide communities in fulfilling the original promise of the Fair Housing Act. The proposed rule involves refining the fair housing elements of the existing planning process that states, local governments, insular areas, and public housing agencies (program participants) now undertake. The process proposed by this rule assists these program participants to assess fair housing determinants, prioritize fair housing issues for response, and take meaningful actions to affirmatively further fair housing.

As recognized by HUD staff, program participants, civil rights advocates, the GAO, and others, the fair housing elements of current housing and community development planning are not as effective as they could be, do not incorporate leading innovations in sound planning practice, and do not sufficiently promote the effective use of limited public resources to affirmatively further fair housing. The approach

proposed by the rule addresses these issues and strengthens AFFH implementation. It does so by providing data to program participants related to fair housing planning, clarifying the goals of the AFFH process, and instituting a more effective mechanism for HUD's review and oversight of fair housing planning. The proposed rule does not mandate specific outcomes for the planning process. Instead, recognizing the importance of local decision-making, it establishes basic parameters and helps guide public sector housing and community development planning and investment decisions to fulfill their obligation to affirmatively further fair housing. In addition, it helps educate other public sector agencies in their planning and investment decisions, and provides relevant civil rights information to the community and other private and public sector stakeholders.

Summary of Legal Authority

The Fair Housing Act (Title VIII of the Civil Rights Act of 1968, 42 U.S.C. 3601–3619) declares that it is ''the policy of the United States to provide, within constitutional limitations, for fair housing throughout the United States.'' *See* 42 U.S.C. 3601. Accordingly, the Fair Housing Act prohibits discrimination in the sale, rental, and financing of dwellings, and in other housing-related transactions because of race, color, religion, sex, familial status, national origin, or handicap.[1] *See* 42 U.S.C. 3601 *et seq.* Section 808(e)(5) of the Fair Housing Act (42 U.S.C. 3608(e)(5)) requires that HUD programs and activities be administered in a manner affirmatively to further the policies of the Fair Housing Act. The Act leaves it to the Secretary to define the precise scope of the AFFH obligation for HUD's program participants.

Summary of the Major Provisions of the Rule

The proposed rule—in concert with other HUD policies—is structured to provide direction, guidance, and procedures for program participants to promote fair housing choice. The rule promotes these objectives and responds to the GAO's observations by:

a. Refining the current requirement that program participants complete an Analysis of Impediments (AI) with a more effective and standardized Assessment of Fair Housing (AFH), through which program participants would evaluate fair housing challenges and goals using regional and national benchmarks and data tools to facilitate the measurements of trends and changes over time;

b. Improving fair housing assessment, planning, and decision-making by providing data that program participants must consider in their AFHs, thereby aiding program participants establish fair housing goals to address these issues and concerns;

c. Incorporating, explicitly, fair housing planning into existing planning processes, the consolidated plan and PHA Annual Plan, which in turn incorporates fair housing priorities and concerns more effectively into housing, community development, land-use, and other decision-making that influences how communities and regions grow and develop;

d. Encouraging and facilitating regional approaches to addressing fair housing issues, including effective incentives for collaboration across jurisdictions and PHAs, and incorporation of fair housing planning into regionally significant undertakings, such as major public infrastructure investments;

e. Bringing people historically excluded because of characteristics protected by the Fair Housing Act into full and fair participation in decisions about the appropriate uses of HUD funds and other investments, through a requirement to conduct community participation as an integral part of program participants' AFHs; and

f. Establishing an approach to affirmatively further fair housing that calls for coordinated efforts to combat illegal housing discrimination, so that individuals and families can make decisions about where to live, free from discrimination, with necessary information regarding housing options, and with adequate support to make their choices viable.

Through these improvements, the rule seeks to make program participants more empowered to foster the diversity and strength of communities and regions by improving integrated living patterns and overcoming historic patterns of segregation, reducing racial and ethnic concentrations of poverty, and responding to identified disproportionate housing needs of persons protected by the Fair Housing Act. The rule also seeks to assist program participants in reducing disparities in access to key community assets based on race, color, religion, sex, familial status, national origin, or disability, thereby improving economic competitiveness and quality of life.

HUD intends the guidance, data, tools, and procedural improvements provided under this proposed rule to reduce the current data collection burden on program participants. HUD will provide technical assistance and guidance that will allow program participants to spend less time gathering information and more time engaged in conversation with the community regarding the most effective means of advancing their fair housing goals. In addition, HUD is facilitating the integration of previously separate planning processes into a single planning process, to the extent feasible, both to streamline the work that program participants undertake and to support the weaving of fair housing values throughout housing and community development decision-making. Under this new process, program participants will submit assessments on a regular schedule and HUD will review them. In addition to achieving more meaningful fair housing outcomes through direct alignment with related planning and investment processes, HUD expects that the clarity and explicit direction provided by the proposed rule should help program participants comply with their affirmatively furthering fair housing responsibilities. One of HUD's aspirations for the proposed rule is that it will reduce the risk of litigation for program participants. Moreover, HUD's commitment to be an ongoing partner in the process should result submissions that meet the standards for analysis that the proposed rule seeks to establish.

Summary of Costs and Benefits

As detailed in the Regulatory Impact Analysis (found at *www.regulations.gov* under the docket number 5173–P–01–RIA), HUD does not expect a large aggregate change in compliance costs for program participants as a result of the proposed rule. As a result of increased emphasis on affirmatively furthering fair housing within the planning process, there may be increased compliance costs for some program participants, while for others the improved process and goal-setting, combined with HUD's provision of foundational data, is likely to decrease compliance costs. Program participants are currently required to engage in outreach and collect data in order to meet the obligation to affirmatively further fair housing. As more fully addressed in the Regulatory Impact Analysis that accompanies this rule, HUD estimates net annual compliance costs in the range of $3 to $9 million.

Further, HUD believes that the rule has the potential for substantial benefit

[1] Although the term ''disability'' is used today to refer to an individual's physical or mental impairment, the term ''handicap'' is the term used in the Fair Housing Act, as enacted in 1968.

for program participants and the communities they serve. The rule would improve the fair housing planning process by providing greater clarity to the steps that program participants undertake to meaningfully affirmatively further fair housing, and at the same time provide better resources for program participants to use in taking such steps, hopefully resulting in increased compliance and fewer instances of litigation. Through this rule, HUD commits to provide states, local governments, PHAs, the communities they serve, and the general public with local and regional data on patterns of integration, racially and ethnically concentrated areas of poverty, access to key community assets, and disproportionate housing needs based on classes protected by the Fair Housing Act. From these data, program participants should be better able to evaluate their present environment to assess fair housing issues, identify the primary determinants that account for those issues, set forth fair housing priorities and goals, and document these activities.

The rule covers program participants that are subject to a great diversity of local preferences and economic and social contexts across American communities and regions. For these reasons, HUD recognizes there is significant uncertainty associated with quantifying outcomes of the process, proposed by this rule, to identify barriers to fair housing, the priorities of program participants in deciding which barriers to address, the types of policies designed to address those barriers, and the effects of those policies on protected classes. In brief, because of the diversity of communities and regions across the Nation and the resulting uncertainty of precise outcomes of the proposed AFFH planning process, HUD cannot quantify the benefits and costs of polices influenced by the rule. HUD is confident, however, that the rule will create a process that allows for each jurisdiction to not only undertake meaningful fair housing planning, but to have capacity and a well-considered strategy to implement actions to affirmatively further fair housing.

II. Background

A. Legal Authority

The Fair Housing Act (Title VIII of the Civil Rights Act of 1968, 42 U.S.C. 3601–3619), enacted into law on April 11, 1968, declares that it is ''the policy of the United States to provide, within constitutional limitations, for fair housing throughout the United States.'' *See* 42 U.S.C. 3601. Accordingly, the Fair Housing Act prohibits discrimination in the sale, rental, and financing of dwellings, and in other housing-related transactions because of race, color, religion, sex, familial status, national origin, or handicap. *See* 42 U.S.C. 3601 *et seq.* Section 808(e)(5) of the Fair Housing Act (42 U.S.C. 3608(e)(5)), requires that HUD programs and activities be administered in a manner affirmatively to further the policies of the Fair Housing Act. Section 808(d) of the Fair Housing Act (42 U.S.C. 3608(d)) directs other federal agencies to administer their programs relating to housing and urban development in a manner affirmatively to further the policies of the Fair Housing Act, and to cooperate with the Secretary in this effort.

The Fair Housing Act's provisions related to ''affirmatively . . . further[ing]'' fair housing, contained in sections 3608(d) and (e), extend beyond the Act's anti-discrimination mandates. *See, e.g., Otero* v. *N.Y. City Hous. Auth.,* 484 F.2d 1122 (2d Cir. 1973); *Shannon* v. *HUD,* 436 F.2d 809 (3d Cir. 1970). When the Fair Housing Act was originally enacted in 1968 and amended in 1988, major portions of the statute involved the prohibition of discriminatory activities (whether undertaken with a discriminatory purpose or with a discriminatory impact) and how private litigants and the government could enforce these provisions.

In section 3608 of the Fair Housing Act, however, Congress went further by mandating that ''programs and activities relating to housing and urban development'' be administered ''in a manner affirmatively to further the purposes of this subchapter.'' Congress has repeatedly reinforced this mandate, requiring in the Housing and Community Development Act of 1974, the Cranston-Gonzalez National Affordable Housing Act, and in the Quality Housing and Work Responsibility Act of 1998, that covered HUD program participants certify as a condition of receiving federal funds that they will affirmatively furthering fair housing. *See* 42 U.S.C. 5304(b)(2), 5306(d)(7)(B), 12705(b)(15), 1437C–1(d)(16).[2]

In examining the legislative history of the Fair Housing Act and related statutes, courts have found that the purpose of the AFFH mandate is to ensure that recipients of federal housing and urban development funds do more than simply not discriminate: it obligates them to take proactive steps to address segregation and related barriers for those protected by the Act, particularly as reflected in racially and ethnically concentrated areas of poverty. The United States Supreme Court, in one of the first Fair Housing Act cases it decided, referenced the Act's co-sponsor, Senator Walter F. Mondale, in noting that ''the reach of the proposed law was to replace the ghettos 'by truly integrated and balanced living patterns.' '' *Trafficante* v. *Metro. Life Ins. Co.,* 409 U.S. 205, 211 (1972).[3] The Act recognized that ''where a family lives, where it is allowed to live, is inextricably bound up with better education, better jobs, economic motivation, and good living conditions.'' 114 Cong. Rec. 2276–2707 (1968). As the Second Circuit has stated, section 3608(d) requires that ''[a]ction must be taken to fulfill, as much as possible, the goal of open, integrated residential housing patterns and to prevent the increase of segregation, in ghettos, of racial groups whose lack of opportunity the Act was designed to combat.'' *Otero,* 484 F.2d at 1134.

The Act leaves it to the Secretary to define the precise scope of the AFFH obligation for HUD's program participants. Over the years, courts have provided some guidance for this task. In the first appellate decision interpreting section 3608, for example, the Third Circuit emphasized the importance of racial and socioeconomic data to ensure that ''the agency's judgment was an informed one'' based on an

[2] Section 104(b)(2) of the Housing and Community Development Act (HCD Act) (42 U.S.C. 5304(b)(2)) requires that, to receive a grant, the state or local government must certify that it will affirmatively further fair housing. Section 106(d)(7)(B) of the HCD Act (42 U.S.C. 5306(d)(7)(B)) requires a local government that receives a grant from a state to certify that it will affirmatively further fair housing. The Cranston-Gonzalez National Affordable Housing Act (NAHA) (42 U.S.C. 12704 *et seq.*) provides in section 105 (42 U.S.C. 12705) that states and local governments that receive certain grants from HUD must develop a comprehensive housing affordability strategy to identify their overall needs for affordable and supportive housing for the ensuing 5 years, including housing for homeless persons, and outline their strategy to address those needs. As part of this comprehensive planning process, section 105(b)(15) of NAHA (42 U.S.C. 12705(b)(15)) requires that these program participants certify that they will affirmatively further fair housing. The Quality Housing and Work Responsibility Act of 1998 (QHWRA), enacted into law on October 21, 1998, substantially modified the United States Housing Act of 1937 (42 U.S.C. 1437 *et seq.*) (1937 Act), and the 1937 Act was more recently amended by the Housing and Economic Recovery Act of 2008, Public Law 110–289 (HERA). QHWRA introduced formal planning processes for PHAs—a 5-Year Plan and an Annual Plan. The required contents of the Annual Plan included a certification by the PHA that the PHA will, among other things, affirmatively further fair housing.

[3] Reflecting the era in which it was enacted, the Fair Housing Act's legislative history and early court decisions refer to ''ghettos'' when discussing racially concentrated areas of poverty.

institutionalized method to assess site selection and related issues. *Shannon,* 436 F.2d at 821–22. In multiple other decisions, courts have set forth how the section applies to specific policies and practices of HUD program participants. *See, e.g., Otero,* 484 F.2d at 1132–37; *Langlois* v. *Abington Hous. Auth.,* 207 F.3d 43 (1st Cir. 2000); *U.S. ex rel. Anti-Discrimination Ctr.* v. *Westchester Cnty.,* 2009 WL 455269 (S.D.N.Y. Feb. 24, 2009).

In addition to the statutes and court cases emphasizing the requirement of recipients of federal housing and urban development funds to affirmatively further fair housing, Executive Orders have also addressed the importance of complying with this requirement.[4]

B. The Need To Refine the Current AFFH Planning Framework

HUD has approached the AFFH obligation in various ways,[5] and this proposed rule is intended in particular to improve fair housing planning by more directly linking it to housing and community development planning processes currently undertaken by program participants as a condition of their receipt of HUD funds. At the jurisdictional planning level, HUD requires program participants receiving Community Development Block Grant (CDBG), HOME Investment Partnerships (HOME), Emergency Solutions Grants (ESG), and Housing Opportunities for Persons With AIDS (HOPWA) formula funding to undertake an analysis to identify impediments to fair housing choice within the jurisdiction take appropriate actions to overcome the effects of any impediments, and keep records on such efforts. *See* 24 CFR 91.225(a)(1), 91.325(a)(1).[6] Likewise, PHAs must commit, as part of their planning process for PHA Plans and Capital Fund Plans, to examine their programs or proposed programs, identify any impediments to fair housing choice within those programs, address those impediments in a reasonable fashion in view of the resources available, work with jurisdictions to implement any of the jurisdiction's initiatives to affirmatively further fair housing that require PHA involvement, maintain records reflecting those analyses and actions, and operate programs in a manner that is consistent with the applicable jurisdiction's consolidated plan. *See* 24 CFR 903.7(o), 903.15.

Over the past several years, HUD has reviewed the efficacy of these mechanisms to fulfill the AFFH mandate and has concluded that the AI process can be a more meaningful tool to integrate fair housing into program participants' planning efforts. HUD's Fair Housing Planning Guide (Planning Guide), a document issued in 1996, provides extensive suggestions but does not fully articulate the goals that AFFH must advance. In addition, HUD has never provided data to grantees to help frame their analysis, and AIs are not regularly submitted to HUD for review.

These observations are reinforced by a recent report by the GAO entitled ''HUD Needs to Enhance Its Requirements and Oversight of Jurisdictions' Fair Housing Plans,'' GAO–10–905, Sept. 14, 2010. *See http://www.gao.gov/new.items/d10905.pdf* (GAO Report). In this report, the GAO found that there has been uneven attention paid to the AI by local communities in part because sufficient guidance and clarity was viewed as lacking. Specifically, GAO noted the uneven quality of existing AIs and found that ''HUD's limited regulatory requirements and oversight'' contribute to many grantees placing a ''low priority on ensuring that their AIs serve as effective planning tools.'' *Id.* at 1.[7] In its recommendations, GAO emphasized that HUD could assist program participants by providing more effective guidance and technical assistance and the data necessary to prepare fair housing plans.

Stemming from substantial interaction with program participants and advocates, and the GAO Report, HUD's analysis is that the current AI process is insufficiently integrated into the grantees' planning efforts. Many program participants are actively grappling with how issues involving race, ethnicity, disability and other fair housing concerns do and should influence housing and community development planning and actions. HUD has found, however, that program participants must turn to outside consultants to collect data and conduct the analysis, and have little incentive to use this work as part of the consolidated plan or PHA Plan. Moreover, HUD believes that the current process does not fully incorporate refinements that have developed since the Planning Guide was promulgated in the way that innovators in the field address equity in the context of housing and urban development.[8] Especially in a time of limited resources, HUD also believes that it can do more to support program participants in the process, especially through the provision of data, meaningful technical assistance, and guidance.

The need to rethink HUD's approach to how program participants affirmatively further fair housing is reinforced by the fact that program participants are working in an America that is more diverse, with an increasing number of communities becoming more integrated. America has always been a demographically dynamic and diverse nation and its diversity is increasing, with over a third of the American population now nonwhite, Hispanic/Latino, or a combination of races.[9] Within little more than a generation, America is poised to become a nation where traditional minorities are in the majority.[10] The ramifications of this increased diversity encompass a broad array of dimensions, from the growing recognition of the correlation between negative health indicators and patterns of segregation and poverty to the increasing understanding regarding the importance of diversity in business, higher education, and elsewhere to prepare workers for the 21st century

[4] Executive Order 12892, entitled ''Leadership and Coordination of Fair Housing in Federal Programs: Affirmatively Furthering Fair Housing,'' issued January 17, 1994, vests primary authority in the Secretary of HUD for all federal executive departments and agencies to administer their programs and activities relating to housing and urban development in a manner that furthers the purposes of the Fair Housing Act. Executive Order 12898, entitled Executive Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, issued on February 11, 1994, declares that Federal agencies shall make it part of their mission to achieve environmental justice ''by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations.''

[5] These include requirements involving the evaluation of site and neighborhood conditions under which HUD-funded housing development occurs and the affirmative marketing of units to promote integrated residences. *See, e.g.,* 24 CFR 891.125, 941.202, 983.57.

[6] For these programs, the Consolidated Plan is intended as the program participant's comprehensive mechanism to gather relevant housing data, detail housing, homelessness, and community development strategies, and commit to specific actions. These are then updated annually through annual action plans.

[7] The GAO noted that close to 30 percent of the grantees from whom it sought documentation had outdated AIs and that almost 5 percent of the grantees were unable to provide AIs when requested.

[8] *See, e.g.,* Department of Housing & Community Development Massachusetts, *Affirmative Fair Housing and Civil Rights Policy* (Apr. 2009), *http://www.mass.gov/hed/docs/dhcd/hd/fair/affirmativefairhousingp.pdf.*

[9] *See* U.S. Department of Commerce, U.S. Census Bureau, *The White Population: 2010,* (Sept. 2011), *http://www.census.gov/prod/cen2010/briefs/c2010br-05.pdf.*

[10] *See* U.S. Department of Commerce, U.S. Census Bureau, *An Older and More Diverse Nation by Midcentury* Releases: CB08–123 (Aug. 14, 2008), *http://www.census.gov/newsroom/releases/archives/population/cb08-123.html.*

economy.[11] HUD's proposed rule also recognizes other significant shifts, such as those related to persons with disabilities. Demographically, the aging of the population makes physically accessible housing and the preservation of housing choice for people with disabilities increasingly significant.[12]

Research indicates that disparities in access to community assets negatively impact educational and economic outcomes.[13] Sustained exposure to highly distressed neighborhoods is associated with a reduction in children's odds of high school graduation by at least 60 percent,[14] while low-income students who have access to asset-rich neighborhoods with good schools may realize math and reading gains that help close the achievement gap.[15] Given this research, HUD hopes this proposed rule and other efforts would reduce disparities in access to community assets based on race, color, religion, sex, familial status, national origin, or disability.

C. The Proposed AFFH Planning Framework

To promote more effective fair housing planning and assist every program participant to meet requirements related to affirmatively furthering fair housing, HUD proposes in this rule to address directly concerns about the current fair housing planning process by making a number of key changes. These include: (1) A new fair housing assessment and planning tool, the AFH, which replaces the AI, (2) the provision of nationally uniform data that will be the predicate for and help frame program participants' assessment activities, (3) meaningful and focused direction regarding the purpose of the AFH and the standards by which it will be evaluated, (4) a more direct link between the AFH and subsequent program participant planning products—the consolidated plan and the PHA Plan—that ties fair housing planning into the priority setting, commitment of resources, and specification of activities to be undertaken, and (5) a new HUD review procedure based on clear standards that facilitates the provision of technical assistance and reinforces the value and importance of fair housing planning activities.

In terms of the provision of greater clarity regarding the purpose of the fair housing assessment and planning process, the proposed rule will more clearly define the core goals involved in fulfilling program participants' affirmatively furthering fair housing mandate. In doing so, HUD begins with goals long associated with this mandate: addressing patterns of segregation while supporting integrated and integrating communities, as well as seeking to reduce disproportionate housing needs among protected class members.[16] The proposed rule recognizes that segregation is due in part to a historical legacy of discrimination and continues to have adverse impacts, with the dual concentration of poverty and racial and ethnic populations still far too prevalent.[17] Segregation carries a heavy social cost. Numerous studies indicate that segregation negatively impacts minorities' educational attainment, labor market outcomes, physical and mental health, and crime victimization.[18] These negative outcomes translate to lower economic productivity for the Nation as a whole, and increased cost to society in a multitude of ways, from the justice system to the public health infrastructure. The importance of overcoming patterns of segregation and supporting means to advance integration are equally important as applied to persons with disabilities. Programmatically, HUD recognizes and is implementing means to overcome a legacy related to persons with disabilities that reflects a history of inappropriate segregation, institutionalization, and otherwise limited equal access to housing choices.[19]

In refining the current AFFH framework, racially or ethnically concentrated areas of poverty are of particular concern because they couple fair housing issues with other significant local and regional policy challenges. These areas clearly fall in the domain of fair housing, as they often reflect legacies of segregated housing patterns. Of the nearly 3,800 census tracts in this country where more than 40 percent of the population is below the poverty line, about 3,000 (78 percent) are also predominantly minority. Racially or ethnically concentrated areas of poverty merit special attention because the costs they impose extend far beyond their residents, who suffer due to their limited access to high-quality educational opportunities, stable employment, and other prospects for economic success. Because of their high levels of unemployment, capital disinvestment, and other stressors, these neighborhoods often experience a range of negative outcomes such as exposure to poverty, heightened levels of crime, negative environmental health hazards, low educational attainment, and other challenges that require extra attention and resources from the larger communities of which they are a part. Consequently, interventions that result in reducing racially and ethnically concentrated areas of poverty hold the promise of providing benefits that assist both residents and their communities.[20]

The proposed rule acknowledges that the prospects for individual or familial success are influenced by a variety of neighborhood features far more extensive than just housing. These other neighborhood features must be important considerations in seeking to advance fair housing. HUD has consistently recognized that features

[11] *See* Dolores Acevedo-Garcia et. al., *Future Directions in Residential Segregation and Health Research: A Multilevel Approach* Am. J. Public Health Vol. 93(2) p. 215–221 (Feb. 2003) *available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447719/?tool=pubmed*; David R. Williams & Chiquita Collins, *Racial Residential Segregation: A Fundamental Cause of Racial Disparities in Health* Public Health Report Vol. 119 p. 404–416 (Sept.–Oct. 2001) *available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1497358/pdf/12042604.pdf*.

[12] *See* U.S. Department of Health & Human Services, Administration on Aging, *Aging Statistics* (Sept. 1, 2011, 1:17:40 p.m.), *http://www.aoa.gov/aoaroot/aging_statistics/index.aspx*.

[13] *See* Megan A. Turner & Karina Fortuny, *Residential Segregation and Low-Income Working Families,* The Urban Institute (Feb. 2009), *http://www.urban.org/uploadedpdf/411845_residential_segregation_liwf.pdf*.

[14] *See* Wodtke GT et al., (2011), Neighborhood Effects in Temporal Perspective: The Impact of Long-Term Exposure to Concentrated Disadvantage on High School Graduation. American Sociological Review. Vol. 76, No. 5, 713–736.

[15] *See* Heather L. Schwartz, *Housing Policy is School Policy: Economically Integrative Housing Promotes Academic Success in Montgomery County, Maryland* A Century Foundation Report p. 57 (2010), *http://www.rand.org/pubs/external_publications/EP201000161.html*.

[16] In setting forth these two goals, the proposed rule reinforces the proposition that a critical component of addressing segregation is providing support for those communities that are integrated or are integrating. Strategies and actions to promote the effective and long-term viability of these communities is an important component of these fair housing goals.

[17] *See http://www.economicmobility.org/assets/pdfs/PEW_NEIGHBORHOODS.pdf*.

[18] *See, e.g.,* David Card & Jesse Rothstein, *Racial Segregation and the Black-White Test Score Gap,* 91 Journal of Public Economics 2158–218 (2007); Edward L. Glaeser & David Cutler, *Are Ghettos Good or Bad,* 112 The Quarterly Journal of Economics 827–872 (1997); David Weiner, Byron Lutz & Jens Ludwig, *The Effects of School Desegregation on Crime* National Bureau of Economic Research, Working Paper No. 15380 (2009).

[19] It has been HUD's policy to encourage community-based rather than institutional residences for persons with disabilities. In furtherance of the Supreme Court's decision in *Olmstead* v. *L.C.,* 527 U.S. 581(1999), and pursuant to regulations at 24 CFR 8.4(d), HUD promotes housing in the most integrated setting appropriate to the needs of persons with disabilities.

[20] *See* William Julius Wilson, *When Work Disappears: The World of the New Urban Poor* 1996.

other than housing stock are important components assessing the quality of housing opportunities and land use and planning activities.[21] Drawing upon pertinent research,'' [22] the proposed rule incorporates a set of measures designed to assess the extent to which a particular area possesses or is linked to assets that correlate with an increased chance to improve an individual or family's life trajectory. It also proposes to provide program participants with the tools to assess the assets and stressors within a community that impact the quality of life of residents. In addition, the proposed rule notes that shifting residential and development patterns have significant implications for families with children, particularly impacting children's ability to receive a quality education. In setting forth this primary objective and commitment to providing relevant data tools and assessment techniques, the proposed rule attempts to follow the advice provided by the GAO report to give program participants more guidance and tools to prepare more effective fair housing plans.

A second core innovation in the proposed rule involves HUD's provision of data to program participants as a starting point in the fair housing assessment process. This data will be drawn from nationally uniform sources(including data related to education, poverty, transit access, employment, exposure to environmental health hazards, and other critical community assets, as well as nationally uniform local and regional data on patterns of integration and segregation; racial and ethnic concentrations of poverty; disproportionate housing needs based on protected class; and outstanding discrimination findings. The provision of this data will both enable program participants to more knowledgably undertake their AFH and reduce the burden that currently exists for undertaking the AI. The HUD data may be supplemented by available local or regional information. HUD believes that these broader data will greatly assist housing and community development strategies, investments, and other actions to affirmatively further fair housing at the jurisdictional and regional level.

By directly providing nationally uniform information about the fair housing dynamics of regions and communities to 1,200 local governments, all states, the insular areas, and more than 4,000 PHAs, HUD expects that officials, community members, and other stakeholders throughout the Nation will be able to have a more informed and transparent conversation about the fair housing potential of public and private investments, strategies, and initiatives. This offers significant opportunities for innovation and progress, especially given the ways in which this data is expected to enable communities to assess changes over time. Further, having a common, national baseline of fair housing indicators will facilitate coordination and connection with planning and assessment of civil rights implications in other domains closely related to housing and community development, such as transportation, education, employment, and health.

Under the proposed rule, program participants will use HUD data to evaluate patterns of integration and segregation, racial and ethnic concentration of poverty, and disparities in access to valuable community assets and disproportionate housing needs based on protected class and evaluate the primary determinants of these conditions. Program participants will also assess whether laws, policies, or practices limit fair housing choice, as well as the role of public investments in creating, perpetuating, or alleviating the segregation patterns revealed by the assessment. Examples of such laws, policies, or practices include, but are not limited to, zoning, land use, financing, infrastructure planning, and transportation.

A third critical innovation in the proposed rule that also responds directly to the GAO report is the AFH, which replaces the AI, and is completed by program participants with HUD data and guidance. The AFH will help program participants more effectively integrate fair housing concerns into the consolidated plan and PHA planning process. The proposed rule requires program participants to submit their AFH to HUD in advance of the consolidated plan and PHA Plan submission so that the AFH may then inform strategies and actions in those plans. HUD's review of an AFH will be based on standards for acceptance contained in the proposed rule, and an accepted AFH and completion of corresponding requirements related to affirmatively furthering fair housing in the consolidated plan and PHA Plan will be required for HUD to approve those respective plans. HUD will either accept the AFH or provide the program participant with specific reasons for non-acceptance, the actions the program participant needs to take to meet the criteria for acceptance, and, as appropriate, technical assistance to meet AFH requirements.

Once accepted, the AFH will then inform consolidated plan and PHA Plan strategies, more directly and effectively incorporating fair housing planning into the comprehensive housing and planning processes that program participants now use.[23] Consolidated plan program participants will demonstrate how their affordable housing and community development priorities and objectives will affirmatively further fair housing. These program participants will also identify any additional strategies and actions not directly tied to the priorities they are setting forth to further goals of the AFH. Similarly, these program participants will describe actions to affirmatively further fair housing in their annual action plans.

The proposed rule similarly creates a structure for PHAs to cooperate fully in the creation of the AFH and then to use the resulting AFH to inform the PHA planning process, all as a predicate to the PHA certification that it will affirmatively further fair housing. As with consolidated plan program participants, PHAs will incorporate the AFH into the PHA planning process in order to inform strategies and actions in their 5-Year PHA Plans and/or Annual Plans to affirmatively further fair housing. PHAs will have the choice to participate with their local government in preparing the AFH, prepare the AFH independently, or follow the state's AFH. PHAs may adjust their planning cycle over time to assure that the AFH is completed before their PHA Plan work begins. For PHAs that participate in the new collaborative AFH, the resulting analysis is designed to be sufficient to support a 5-year planning horizon, and PHAs will not have to undertake the same exercise every year. This will free up PHA resources to focus on implementation and long-term strategies.

[21] *See, e.g.,* HUD Fair Housing Planning Guide 5–9 (emphasizing that jurisdictions should strive to equalize services, including schools, recreational facilities and programs, social service programs, parks, roads, transportation, street lighting, trash collection, street cleaning, crime prevention, and police protection activities, in their fair housing plan); *see also, e.g.,* 24 CFR 941.202 (requiring that, inter alia, environmental conditions, access to employment opportunities, and access to ''social, recreational, educational, commercial, and health facilities and services, and other municipal facilities and services'' be considered when choosing neighborhoods in which to locate public housing); 24 CFR 891.125.

[22] *See* Xavier de Souza Briggs, *The Geography of Opportunity: Race and Housing Choice in Metropolitan America* (2005).

[23] The consolidated plan is a 5-year planning instrument. The annual action plan is the plan submitted by consolidated plan program participants that describes the consolidated plan actions that participants intend to carry out in a calendar year.

Many fair housing issues transcend local jurisdictional boundaries. Solutions to such issues often involve coordinated actions by multiple jurisdictions, and require creative collaboration across traditionally disconnected policy domains. Coordination between jurisdictions that undertake consolidated planning and PHAs can allow for more effective deployment of limited resources, which is important because PHA programs, including notably the Housing Choice Voucher Program, can frequently be significant mechanisms to enable families to access communities offering assets that are often difficult for voucher families to obtain. In this context, regional assessments can be an important means for effectively addressing these issues, as well as those that are local to independent jurisdictions. Regional assessments are therefore encouraged in this rule.

It is a statutory condition of HUD funding that program participants certify that they will affirmatively further fair housing, which, under the proposed rule, means that that they will take meaningful actions to further the goals identified in an AFH conducted in accordance with the requirements of this rule, and that the program participant will take no action that is materially inconsistent with its obligation to affirmatively further fair housing. It is important to note, however, that neither the proposed rule nor the improved process that it will establish defines the strategies or actions program participants will take. In fact, the proposed rule emphasizes that there are diverse approaches that can be taken. A program participant's strategies and actions may include strategically enhancing neighborhood assets (for example, through targeted investment in neighborhood revitalization or stabilization) or promoting greater mobility and access to communities offering vital assets such as quality schools, employment, and transportation consistent with fair housing goals. Consistent with long-standing judicial guidance regarding AFFH, the proposed rule is designed so that program participants undertake a process that informs and engages the public and allows program participants to make educated judgments regarding the appropriate strategies and actions that are consistent with their obligations to affirmatively further fair housing. In doing so, it directs them to examine relevant factors, such as zoning and other land-use practices that are likely contributors to fair housing concerns, and take appropriate actions in response.

D. Conclusion

The opportunity to choose where one lives free from obstacles related to race, color, religion, sex, familial status, national origin, or disability is essential to the ability to engage as a full member of one's community. This promise of fair housing choice requires vigorous enforcement of laws barring discrimination, and proactive planning, strategies, and actions.

In administering its programs and activities in a manner to affirmatively further fair housing, HUD is committed to taking active measures to build on progress made by communities across the country to affirmatively further fair housing, while confronting the reality that more must be done. This proposed rule, informed by local experience and the GAO report, offers such active measures.

III. Summary of Proposed Rule

This rule proposes to amend the regulations in 24 CFR parts 5, 91, 92, 570, 574, 576, and 903, as discussed in this section.

Affirmatively Furthering Fair Housing Regulations

This proposed rule would amend HUD regulations in 24 CFR part 5 that contain general HUD program requirements, and specifically 24 CFR part 5, subpart A, which contains generally applicable definitions and federal requirements that are applicable to all or almost all HUD programs. This rule proposes to add new §§ 5.150–5.180 under the undesignated heading of ''Affirmatively Furthering Fair Housing.'' These new sections will primarily provide the regulations that will govern the affirmatively furthering fair housing planning process by states, local governments, and PHAs, but reserves additional sections in subpart A for HUD to continue to provide regulations that will assist all HUD program participants in more effectively affirmatively furthering fair housing.

Purpose of Affirmatively Furthering Fair Housing Regulations (§ 5.150). New § 5.150 states that the purpose of HUD's new regulations (AFFH regulations) is to provide more effective means of meeting the statutory obligation imposed on HUD program participants to affirmatively further fair housing. The new AFFH regulations are intended to add clarity to the goals that are at the heart of affirmatively furthering fair housing, to provide for guidance and interaction between HUD and program participants and, to the extent appropriate, inform other housing and urban development programs that are subject to AFFH requirements. The new regulations envision a process that is structurally incorporated into the consolidated plan and the PHA planning process, building upon what is already familiar to HUD program participants and thus reducing burden and connecting disparate planning processes.

Definitions (§ 5.152). New § 5.152 provides the definitions that are used in the AFFH regulations. Several terms defined in this section are defined in other HUD regulations, and this section contains cross-references to the regulations that define such terms. New terms defined in this section include ''*affirmatively furthering fair housing,*'' ''*assessment of fair housing, community participation,*'' ''*disproportionate housing needs,*'' ''*fair housing choice,*'' ''*fair housing determinant,*'' ''*fair housing issue,*'' ''*fair housing enforcement and fair housing outreach capacity,*'' ''*integration,*'' ''*racially or ethnically concentrated area of poverty,*'' ''*segregation,*'' and ''*significant disparities in access to community assets.*'' For disproportionate housing needs, integration, racially or ethnically concentrated area of poverty, segregation, and significant disparities in access to community assets, HUD will provide specific data sources and thresholds with the final rule and will update this information periodically through **Federal Register** notices, as data sources and methodologies improve.

The definition of ''*affirmatively furthering fair housing*'' clarifies that AFFH, while including antidiscrimination measures, requires proactive steps to foster more inclusive communities and access to community assets for all those protected by the Fair Housing Act. The definition incorporates the goals animating the proposed rule, as reflected in the categories of the AFH (*see* § 5.154) and described in the preamble, see Introduction, Parts I and II. It makes clear that the pursuit of these ends requires appropriate assessment and analysis, and actions based on this assessment and analysis. When compared to the definition of AFFH contained in the Planning Guide, this definition provides greater clarity about the purposes of AFFH, while retaining that AFFH will be accomplished through analysis and assessment and actions (including the investment of federal and other resources and implementation of strategies) based upon that analysis and assessment. The

proposed definition encompasses the key aspects of the definition incorporated in the Planning Guide, as satisfactory production of an AFH will require identifying what were previously called impediments, taking actions, and maintaining records. Certain terms that are in the Planning Guide definition do not need to be included in the proposed definition, as they are incorporated elsewhere in the rule.

The definition of ''*fair housing choice''* sets forth elements required for individuals and families to be able to live where they choose without barriers related to the classes protected under the Fair Housing Act: Actual choice, protected choice, and enabled choice. As explained in more detail in the preamble (see Introduction, Part II (B)), these elements are necessary for individuals and families to be able to achieve fair housing choice given the legacy of segregation, ongoing discrimination, and residential patterns that offer different levels of access to community assets.

The definition of ''*fair housing issue''* similarly builds on the core elements of AFFH as contained in that definition and fully explained in the preamble, and incorporates any other condition that impedes fair housing choice.

The definitions of ''*integration,''* ''*segregation,''* ''*racially or ethnically concentrated areas of poverty,''* and ''*significant disparities in access to community assets''* are included because they are key components of the goals contained in the proposed rule and central elements in the new AFH; see § 5.154. When appropriate, they identify cross-references to other legal standards that are relevant to how these terms apply to specific classes protected under the Act (e.g., integration and persons with disabilities). The definitions of ''*integration,''* ''*segregation,''* and ''*racially or ethnically concentrated areas of poverty''* note that HUD will determine the appropriate data sources in addition to the decennial status to be used to identify such geographic areas.

Assessment of Fair Housing (AFH) (§ 5.154). New § 5.154 sets forth the key requirement for more effectively fulfilling the duty to affirmatively further fair housing—an assessment of fair housing (AFH) by program participants. As discussed earlier, HUD has determined that the current process for affirmatively furthering fair housing is insufficient to ensure that program participants are meeting their obligation in a purposeful manner as contemplated by law. The AFH, which will be developed with data and guidance from HUD, will replace the AI previously required of program participants, which often required significant staff and other resources to complete without adequately informing subsequent planning and action. The result will not only be evidence that program participants have undertaken meaningful fair housing planning, but that they have a well-considered strategy to implement actions to affirmatively further fair housing. HUD believes that the process set forth in this proposed rule involving the submission and review of the AFH will thus lead to a more effective and collaborative fair housing planning process, especially since HUD is clarifying the goals and requirements of the process, providing data and other prerequisites, and integrating the AFH into other key planning documents for the use of HUD funds.

Paragraph (b) of this section lists the HUD program participants that must perform such assessment, and these entities are: (1) States, insular areas, and local governments participating in HUD programs that are covered by the consolidated plan submission requirements in HUD regulations in 24 CFR part 91; and (2) PHAs receiving assistance under sections 8 and 9 of the U.S. Housing Act of 1937 . Currently, as noted, in support of the affirmatively furthering fair housing certification of the Consolidated Plan statute, 42 U.S.C. 10275(b)(15), HUD requires program participants that receive formula grants under the CDBG, ESG, HOME, and HOPWA programs to prepare an AI. *See* 24 CFR 91.2(a), 91.225(a), 91.325(a), 91.425(a). Also, in support of the civil rights certification of the PHA Plan statute, 42 U.S.C. 1437c–1(d)(15), HUD requires PHAs to examine their programs for impediments to fair housing choice. *See* 24 CFR 903.7(o).

Paragraph (c) provides that HUD will make available fair housing data to program participants to assist them in their assessment of the availability of fair housing choice in their jurisdictions and in overcoming barriers to such choice. In addition to any available local or regional information and information gained through community participation and consultation, HUD will provide, as a resource for program participants, a set of nationally uniform local and regional data on patterns of integration and segregation; racially and ethnically concentrated areas of poverty; access to neighborhood opportunities such as education, employment, low poverty, transportation, and environmental health, among others; disproportionate housing needs; data on individuals with disabilities and families with children; and discrimination. HUD will also provide PHA site locational data (including, to the extent available, units accessible for persons with disabilities), the distribution of housing choice vouchers, and occupancy data.

HUD proposes using the data and thresholds specified in the data methodology appendix, the full details of which can be found at *www.regulations.gov* under docket number 5173–P–01–DM. To describe segregation dynamics, HUD will provide common social science measures of segregation, including the dissimilarity index and the isolation index. These measures will be accompanied by guidance to help program participants and others understand whether values suggest relatively low, moderate, or high levels of segregation. HUD will also provide data on disproportionate housing needs for protected classes, analogous to what is provided in HUD's consolidated planning process. Further, HUD will provide data to program participants that reports on the existence of racially concentrated areas of poverty (RCAP) in their jurisdictions. These data will include a designation that identifies whether a given census tract is an RCAP, based on HUD-established joint thresholds for minority and poverty concentrations.

Finally, HUD has constructed key measures along an array of important categories. A simple poverty index captures the depth and intensity of poverty in a given neighborhood. The neighborhood school proficiency index uses school-level data on the performance of students on state exams to describe which neighborhoods have more proficient elementary schools and which have less proficient elementary schools. A labor market engagement index provides a summary description of the relative intensity of labor market engagement and human capital in a neighborhood. A job access index summarizes the accessibility of a given residential neighborhood as a function of its distance to all job locations, with distance to larger employment centers weighted more heavily. A health hazards exposure index summarizes potential exposure to harmful toxins emitted from industrial facilities at a neighborhood level. A transit index reflects a neighborhood's proximity to transit stops. The input variables for each index are listed below, with more detail on the construction of each measure available in the data appendix referenced above.

Dimension	Input variables
Poverty Index	Percent of families living below the poverty line and percent of households receiving public assistance.
School Proficiency Index	Percent of elementary students who are proficient in reading and percent who are proficient in math according to state examinations.
Labor Market Engagement/Human Capital Index.	Neighborhood unemployment rate; neighborhood labor force participation rate; and percent of the population over the age of 25 with a bachelor's degree or higher.
Job Access Index	Number of jobs in a neighborhood; distance from a neighborhood to employment centers; and number of workers commuting to those employment centers.
Health Hazards Exposure Index	Distance to facilities in EPA's Toxic Release Inventory database; volume of releases; and toxicity of released chemicals.
Transit Access	Distance to nearest fixed-rail or bus rapid transit station.

As with all data metrics, the measures in each category have strengths, as well as limitations. Limitations arise in particular in this instance because the metrics must rely on nationally available data, which are often coarser than data available for some localities. For example, measures for schools are reliant on broadly available test score information and not detailed measures of instructional quality, while measures of transit may not reflect the multitude of transit options (bus, trolley, ferry) in some communities. Program participants will have the flexibility to supplement or replace HUD measures when better local alternatives exist. Moreover, because research on measuring access to community assets is continually evolving, HUD is committed to reviewing the data on an ongoing basis for potential improvements.

Specific solicitation of comment. Because these data are important and novel, HUD is seeking input on these data metrics, both in the context of this rule, as well as in a separate upcoming public comment process. This supplemental process will focus more directly on technical aspects of the strengths and limitations of specific metrics. Nonetheless, HUD seeks comment on the strengths and limitations of the proposed data. HUD is also interested in potential quantitative or qualitative data that are not currently included in the indicators that might effectively complement or replace the HUD-provided data.

Paragraph (d) provides the content of the AFH that a program participant must submit to HUD. Paragraph (d) provides that the AFH must address segregation, concentration of poverty, disparities in access to community assets, and disproportionate housing needs based on race, color, religion, sex, familial status, national origin, or handicap. In addressing these subject areas, paragraph (d) provides that the AFH must include a summary of fair housing issues in the jurisdiction, including any findings or judgments related to fair housing or other civil rights laws and assessment of compliance with existing fair housing laws, regulations, and guidance. Additionally, the AFH must assess the jurisdiction's fair housing enforcement and fair housing outreach capacity.

Paragraph (d) also provides for the AFH to include an analysis of the data concerning disparities in the jurisdiction's area, based upon HUD-provided fair housing data, as well as local or regional data available to the jurisdiction, and community input. Using this information, the program participant must identify, within the jurisdiction and region, integration and segregation patterns and trends across protected classes; racially or ethnically concentrated areas of poverty; whether significant disparities in access to community assets exist across protected classes within the jurisdiction and region; and whether disproportionate housing needs exist across protected classes.

Paragraph (d) further provides that, using an assessment tool provided by HUD, each program participant must: (1) Identify the primary determinants influencing conditions of segregation; concentrations of poverty; disparities in access to community assets; and disproportionate housing needs based on protected class; and the most significant determinants of these disparities; (2) identify fair housing priorities and general goals and articulate a justification for the chosen prioritization; and (3) set one or more goal(s) for mitigating or addressing the determinants. In recognition of the proposition that this assessment will be part of existing statutory planning processes, paragraph (d) provides that the specific strategies or funding decisions subject to the consolidated plan, PHA Plan, or other relevant planning processes are not required to be detailed in an AFH. It is HUD's expectation that the AFH will also serve as a valuable tool to inform other planning documents or processes in addition to the consolidated plan and PHA Plan, such as PHA Capital Fund Plans, and transportation or education plans, in this way facilitating and supporting civil rights planning across policy domains.

Paragraph (e) addresses AFH requirements for specific types of program participants. This paragraph addresses the AFH required for: (1) PHAs that participate with the relevant consolidated plan program participant; (2) HOME Program Consortia; (3) Insular Areas; and (4) the District of Columbia. With respect to PHAs, this paragraph provides a process for submission and review of a dissenting statement or alternative views on an AFH created with a consolidated plan program participant. With respect to preparation and submission of an AFH, a HOME Program consortium is considered to be a single unit of general local government. An insular area jurisdiction may choose to prepare an AFH following either the abbreviated AFH procedures in 24 CFR 91.235, or the complete AFH procedures applicable to local governments in 24 CFR part 91, subpart C. The District of Columbia must follow the requirements applicable to local governments described in this subpart.

Regional AFHs (§ 5.156). New § 5.156 addresses and encourages regional assessments and fair housing planning, providing that that two or more program participants may join together to submit a single AFH to evaluate fair housing challenges, issues, and determinants from a regional perspective (Regional AFH). Regionally collaborating program participants need not be contiguous and may cross state boundaries, and a Regional AFH, like a local AFH, will examine regional data and account for regional dynamics. Regionally collaborating program participants must designate one member as the lead entity to oversee the development and submission of the assessment.

Program participants are encouraged to cooperate to develop regional AFHs to achieve the sharing of resources and the development of regional strategies, goals, and outcomes to improve fair housing choice for individuals within regional areas. A consolidated plan program participant choosing to

participate in a Regional AFH should consider the implications of this approach on its consolidated plan. Each cooperating consolidated plan program participant remains responsible for its own consolidated plan and its obligation to affirmatively further fair housing in accordance with the consolidated plan and applicable program requirements. This section does not preclude program participants from entering into other cooperative arrangements to undertake regional fair housing assessments and planning.

While new § 5.156 encourages regional assessments, a regional assessment does not relieve each regionally collaborating program participant from its obligation to analyze and address local fair housing issues and determinates that affect housing choice within its respective jurisdiction.

Community participation, consultation, and coordination (§ 5.158). New § 5.158 provides for community participation and consultation requirements for the purpose of ensuring that the AFH is informed by meaningful community participation and is integrated fully into the consolidated plan process, or other planning processes, as may be applicable. Section 5.158 specifies the minimum AFH community participation and consultation that must be undertaken, whether preparing the AFH singly or in combination with other program participants. For consolidated plan program participants, § 5.158 provides that a jurisdiction must follow the policies and procedures described in its applicable citizen participation plan adopted pursuant to the consolidated plan regulations in 24 CFR part 91 (specifically, 24 CFR 91.105, 91.115, 91.401). This section also requires that the jurisdiction consult with the agencies and organizations identified in consultation requirements at 24 CFR part 91 (specifically, 24 CFR 91.100, 91.110, 91.235, 91.401). For PHAs, § 5.158 provides that PHAs must follow the policies and procedures described in 24 CFR 903.7 and 903.19.

Paragraph (b) of § 5.158 addresses coordination and provides that PHAs may participate directly with jurisdictions, prepare their own AFH, or adopt a state's AFH.

AFH Submission Requirements (§ 5.160). New § 5.160 provides the requirements for submission of the AFH to HUD, and provides that the first time a program participant is undertaking the assessment, it must submit its AFH to HUD at least 270 calendar days before the start of the program year prior to the start of the 3- or 5-year consolidated planning process. This section provides an exception for the date on which newly eligible jurisdictions under the HOME program must submit an AFH. Under 24 CFR 92.104, newly eligible jurisdictions shall submit an initial AFH not later than 90 calendar days after providing notification under § 92.103 that the jurisdiction intends to participate in the HOME program as a participating jurisdiction.

New § 5.160 provides that, after acceptance of a program participant's initial AFH, each program participant shall submit subsequent AFHs to HUD at least 195 calendar days before the start of the jurisdiction's program year in which they are submitting a consolidated plan. The submission dates set forth in this section, both for an initial AFH and subsequent AFHs, are established to allow the results of an accepted AFH to inform the consolidated plan and PHA planning process.

Specific solicitation of comment. HUD specifically invites comments as to whether these time frames will achieve that objective.

New § 5.160 also addresses late submission of an AFH. Paragraph (b) of this section provides that an AFH accepted by HUD is a precondition for acceptance of the AFFH certification that is required for the consolidated plan and the PHA Plan. Paragraph (b) also provides that, if a jurisdiction fails to submit its AFH in a timely manner, HUD may require that the jurisdiction submit its consolidated plan within a corresponding period of time after that. However, in no event will the deadline be extended past August 16 of the federal fiscal year in which grant funds are appropriated, as provided in 24 CFR 91.15. Thus, as provided under the consolidated plan regulations, the failure to submit the consolidated plan by August 16 results in the loss of covered funds for the program participant for that funding year. *See* 24 CFR 91.15 (a)(2).

Paragraph (c) of § 5.160 addresses the frequency of submission of an AFH, and provides that each consolidated plan program participant must submit an AFH at least once every 5 years, or at such time agreed upon by HUD and the program participants in order to coordinate AFH submission with time frames required of consolidated plans, cooperation agreements, or other plans. PHAs participating with their consolidated plan program participants in the AFH process will incorporate the resulting AFH into its PHA Plan every 5 years, and PHAs choosing to undertake their own AFH will further have to update their AFH annually. Program participants will thus be in a position to coordinate the AFH process with existing planning processes.

Paragraph (d) of § 5.160 provides that a consolidated plan program participant or a PHA may request to change a program year start date or fiscal year beginning date to better coordinate the submission of the AFH, consolidated plan, and PHA Plan.

Review of AFH (§ 5.162). New § 5.162 addresses review of AFHs by HUD. HUD's review of an AFH is to determine whether the program participant has met the requirements for providing its analysis, assessment, and goal setting as set forth in § 5.154(d). This section provides that the AFH will be deemed accepted 60 calendar days after the date that HUD receives the AFH for review, unless before that date HUD has notified the program participant that the AFH is not accepted. This section provides that HUD will notify program participants in writing that the AFH has not been accepted, and the written notification will specify the reasons that the AFH was not accepted and the actions that program participants may take to meet the criteria for acceptance. Section 5.162 allows program participants to revise and resubmit AFHs within 45 calendar days after the date of the first notification of non-acceptance. The revised AFH will be deemed accepted after 30 calendar days of the date by which HUD receives the revised AFH, unless before that date HUD has provided notification that HUD does not accept the revised AFH. These time frames generally parallel the framework through which HUD currently reviews consolidated plan submissions.

HUD's acceptance of an AFH means only that, for purposes of administering HUD program funding, HUD has determined that the program participant has provided the required elements of an AFH as set forth in § 5.154(d). HUD's acceptance does not mean that HUD has determined that a jurisdiction has complied with its obligation to affirmatively further fair housing under the Fair Housing Act; has complied with other provisions of the Act; or has complied with other civil rights laws, regulations or guidance.

Revising the AFH (§ 5.164). New § 5.164 establishes the minimum criteria that will require a program participant to revise its AFH.

Paragraph (a) of this section provides that if a program participant experiences a significant material change in circumstances that calls into question the continued validity of the AFH, then the program participant must revise its AFH.

Paragraph (a)(1) provides examples of what a significant material change in circumstances may be, which would include: The jurisdiction is in an area for which the President has declared a disaster under title IV of the Robert T. Stafford Disaster Relief and Emergency Assistance Act that is significant; the jurisdiction has experienced significant demographic changes; the jurisdiction has made significant policy changes, such as significant changes related to zoning, housing plans or policies, or development plans or policies; or the jurisdiction is subject to significant civil rights findings, determinations, Voluntary Compliance Agreements, or other settlements. This section also provides that a program participant must revise its AFH upon written notification by HUD in which HUD specifies the significant material change that HUD has found to have taken place, thus requiring a revision to the AFH. Required revisions will be practical and focused on the relevant underlying change in circumstances, rather than necessarily requiring revision to the entire AFH. This section recognizes that population, demographic, and other data may not be accurate when there are sudden shifts in circumstances, and it is important for program participants to examine the information that is available to them at the time.

Paragraph (a)(2) of § 5.164 requires consolidated plan program participants, in their citizen participation plans adopted in accordance with the consolidated plan regulations in 24 CFR part 91, to specify the criteria that the program participant will follow in determining which significant material changes will require revisions to AFH. Paragraph (a)(2) specifies that the criteria must include, at a minimum, the criteria described in paragraph (a)(1) of § 5.164.

Paragraph (b) of § 5.164 provides that revisions to the AFH are subject to community participation. This requirement underscores the importance of the jurisdiction's community being involved in the development of the AFH, including significant changes to the AFH. Paragraph (b) provides that the jurisdiction must follow the notice and comment process applicable to consolidated plan substantial amendments and the jurisdiction's citizen participation plan adopted in accordance with the consolidated plan regulations at 24 CFR part 91; specifically, §§ 91.105, 91.115. Paragraph (b) requires that a consortium must follow the participation process applicable to consolidated plan substantial amendments under the consortium's citizen participation plan adopted pursuant to the consolidated plan regulations 24 CFR 91.401.

Paragraph (c) of § 5.164 provides that revisions to the AFH must be submitted to HUD and will be reviewed pursuant to the process set forth in § 5.162.

Paragraph (d) of § 5.164 provides that when an AFH is revised under this subpart, PHAs must revise their PHA Plan within 18 months pursuant to 24 CFR 903.15(e).

As this section reflects, HUD has established requirements for revisions to the AFH that closely follow the requirements for consolidated plan substantial amendments, thereby providing a process with which consolidated plan program participants are thoroughly familiar and that can readily be adopted by PHAs.

Recordkeeping (§ 5.166). This section establishes AFFH-related recordkeeping requirements for program participants. The maintenance of the information that formed the development of the AFH, including information obtained through consultation and community participation, is important for purposes of demonstrating why the AFH contains the strategies and actions that it does, and by inspection by HUD if HUD determines the need to examine the underlying information that resulted in the AFH. This section lists the specific documents that program participants are to maintain and provides that these records must be maintained for the period specified in program regulations.

As this preceding discussion of the new AFFH regulations reflect, these new regulations, and specifically the new AFH, are established not only to reflect the importance of undertaking fair housing planning well, but to underscore that fair housing planning is an integral part of the consolidated and PHA planning processes.

Conforming Amendments Consolidated Plan Regulations (24 CFR Part 91)

Because the AFFH regulations in 24 CFR part 5 build on existing consolidated plan regulations with respect to consultation, community participation, submission, and revisions, conforming amendments to the consolidated plan regulations must be made to reflect the incorporation of the AFH into the consolidated planning process.

Definitions (§ 91.5)

Section 91.5, the definition section of HUD's consolidated plan regulations, would be revised to reflect that the terms ''*affirmatively furthering fair housing,*'' ''*Assessment of Fair Housing or AFH and protected class*'' are defined in 24 CFR part 5.

Consultation; Local Governments (§ 91.100)

Section 91.100 of HUD's consolidated plan regulations would be amended in paragraph (a) to include the AFH in the consultation that a local government is required to undertake. With respect to the AFH, paragraph (a) requires the local government to consult with the same public and private agencies that the local government consults with in preparing the consolidated plan, but adds that such consultation shall also include any community- and regionally-based organizations that represent protected class members or advance fair housing laws.

Paragraph (c) of § 91.100, which requires the local government to consult with the local PHA, would be amended to provide that the jurisdiction must consult with the PHA regarding the AFH, affirmatively furthering fair housing strategies, and proposed actions to affirmatively further fair housing.

The proposed rule adds a new paragraph (e) to § 91.100 to address the requirement to affirmatively further fair housing. Paragraph (e) provides that the local government shall consult with community- and regionally based organizations that represent protected class members or enforce fair housing laws, such as state or local fair housing enforcement agencies (including participants in the Fair Housing Assistance Program (FHAP), fair housing organizations and other nonprofit organizations that receive funding under the Fair Housing Initiative Program (FHIP), and other public and private fair housing service agencies, to the extent such entities operate within its jurisdiction.

As noted in paragraph (e), this consultation will help provide a better basis for the local government's AFH, its certification to affirmatively further fair housing and other portions of the consolidated plan concerning affirmatively furthering fair housing. Paragraph (e) provides that the consultation required under this paragraph can occur with any organizations that have the capacity to engage with data informing the AFH and are sufficiently independent and representative to provide meaningful feedback to a jurisdiction on the AFH, the consolidated plan, and their implementation. A Fair Housing Advisory Council, or similar group, that includes community members and advocates, fair housing experts, housing and community development industry participants, and other key stakeholders can meet this critical consultation requirement.

The proposed rule requires consultation to occur throughout the fair housing planning process, meaning that the jurisdiction will consult with the organizations described in this section in the development of both the AFH and the consolidated plan. The AFFH-related consultation on the consolidated plan shall specifically seek input into how the goals identified in the accepted AFH inform the priorities and objectives of the consolidated plan. This community input and consultation is critical to understanding fair housing issues through the AFH and incorporating that understanding into the consolidated plan.

Citizen Participation Plan; Local Governments (§ 91.105)

This section is amended to include the AFH in the requirements governing the local government's citizen participation plan. While reference to the AFH is made throughout § 91.105, the amendments to specifically note are as follows:

Paragraph (a)(2)(i) of this section would be amended to add explicit reference to residents and other interested parties that are encouraged to participate in the development of the AFH, and significant revisions to the AFH, along with participation in the development of the consolidated plan and substantial amendments to the consolidated plan.

Paragraph (a)(2)(ii), which encourages the participation of local and regional institutions, would be amended to reflect that such participation is not only important to the consolidated plan but to the AFH as well.

Paragraph (a)(2)(iii) of this section, which addresses consultation with PHAs, would be amended to include consultation with any resident advisory boards, resident councils, and resident management corporations.

The proposed rule adds a new paragraph (a)(4) to § 91.105 to require a local government to describe in its citizen participation plan the jurisdiction's procedures for assessing language needs in its area and to identify any need for translation of notices and other vital documents. New paragraph (a)(4) also provides that, at a minimum, the citizen participation plan shall require that the local government take reasonable steps to provide language assistance to ensure meaningful access to citizen participation by persons with Limited English Proficiency. This requirement reflects that local government across the Nation consist of individuals of many different backgrounds, including members of the community for which English is not their first language and therefore they lack the proficiency that may be needed to be fully involved in community affairs. This requirement strives to have local governments involve these individuals to the maximum extent possible.

Paragraph (b) of § 91.105 would be amended to provide that the local government's citizen participation plan must require that, as soon as practical after HUD makes data for the AFH available to the local government, the local government must make such information, and any other supplemental information that the local government plans to incorporate into its AFH, available to the public, public agencies, and other interested parties.

Paragraph (c) of § 91.105 would be amended to divide the existing paragraph into two subparagraphs. Paragraph (c)(1)(i) addresses the existing requirement concerning the local government to specify the criteria that a jurisdiction will follow in determining what changes in the local government's planned or actual activities constitute a substantial amendment to the consolidated plan. Paragraph (c)(1)(ii) would provide that the local government must specify the criteria the local government will use for determining when significant revisions to the AFH will be appropriate, and provides that, at a minimum, the local government's criteria must include the criteria specified in 24 CFR 5.164.

Paragraph (e) of § 91.105 would be amended to revise paragraph (1) into two subparagraphs. Paragraph (e)(1)(i) addresses the existing requirement for the number of public hearings to hold on the jurisdiction's consolidated plan. Paragraph (e)(1)(ii) would address the public hearing for the AFH and requires the local government to provide at least one public hearing before the proposed AFH is published for comment

Paragraphs (f), (g), (h), (i), (j), and (l) would each be revised to reference the AFH.

Consultation; States (§ 91.110)

This section would be revised to provide for the AFH to be subject to the same consultation requirements as state consolidated plans. Two new subparagraphs would be added to paragraph (a) of this section.

Paragraph (a)(1) would specifically address consultation pertaining to public housing, with the objective to ensure that the PHA Plan is consistent with the consolidated plan.

Paragraph (a)(2) would address consultation pertaining to affirmatively furthering fair housing, with the objective to ensure that there is a meaningful assessment of fair housing.

Citizen Participation Plan; States (§ 91.115)

The proposed rule would amend paragraph (a)(1) of § 91.115 to provide for a new effective date for the new provisions being added to this section pertaining to the AFH. References to the AFH would also be added to paragraph (a)(2) of this section. The amendments to this section include adding a new paragraph (a)(4) that would require reasonable efforts to provide language assistance to non-English-speaking residents.

Paragraph (b) of this section, which addresses development of the consolidated plan, would be amended to address development of the AFH in addition to the consolidated plan.

Paragraph (c) of this section, which addresses criteria for amending the consolidated plan, would be revised to also address the criteria for amending the AFH.

Paragraphs (f), (g), and (h) of this section, which address availability of information to the public, access to records, and complaints, respectively, would be amended to reference the AFH.

Strategic Plan (§ 91.215)

This section of the consolidated plan regulations describes the prescribed content of the local government's strategic plan. This proposed rule adds to this section a new paragraph (a)(5) that requires the jurisdiction's consolidated plan to describe how the priorities and specific objectives of the jurisdiction will affirmatively further fair housing, and that the description should be done by setting forth strategies and actions consistent with the goals and other elements identified in an AFH conducted in accordance with § 5.154. New paragraph (a)(5) provides that for issues not addressed by these priorities and objectives, the plan must identify additional objectives and priorities for affirmatively furthering fair housing.

Action Plan (§ 91.220)

This section of the consolidated plan regulations lists the items that comprise a local government's action plan. Paragraph (k) of § 91.220 is divided into two subparagraphs. Paragraph (k)(1) requires the action plan to address the actions that the local government plans to take during the next year to address fair housing issues identified in the AFH. Paragraph (k)(2) addresses the existing provision of paragraph (k), which is the requirement of the local

government to list the actions that it plans to take to address, among other things, obstacles to meeting underserved needs, and fostering and maintaining affordable housing.

Certifications (§ 91.225)

The proposed rule would amend paragraph (a)(1) of this section to provide that the local government's certification that it will affirmatively further fair housing means that the local government will take meaningful actions to further the goals identified in the AFH conducted in accordance with the requirements of 24 CFR 5.154, and that it will take no action that is materially inconsistent with its obligation to affirmatively further fair housing.

Monitoring (§ 91.230)

The proposed rule revises this section to provide that a local government's monitoring of its activities carried out in furtherance of the consolidated plan, must include monitoring of strategies and actions that address the fair housing issues identified in the AFH.

Special Case: Abbreviated Consolidated Plan (§ 91.235)

Paragraph (c) of this section, which defines what is an abbreviated plan, is revised to provide that the abbreviated plan must describe how the jurisdiction will affirmatively further fair housing by addressing issues identified in an AFH conducted in accordance with 24 CFR 5.154.

Strategic Plan (§ 91.315)

This section of the consolidated plan regulations describes the prescribed content of the state government's strategic plan. The changes made to this section mirror the changes made to § 91.215.

Action Plan (§ 91.320)

This section of the consolidated plan regulations describes the prescribed content of the state government's action plan. The changes made to this section mirror the changes made to § 91.315, but are found in paragraph (j) of § 91.320.

Certifications (§ 91.325)

Similar to the amendment to § 91.225, the proposed rule would amend paragraph (a)(1) of § 91.325 to provide that the state's certification that it will affirmatively further fair housing means that the state will take meaningful actions to further the goals identified in the AFH conducted in accordance with the requirements of 24 CFR 5.154, and that it will take no action that is materially inconsistent with its obligation to affirmatively further fair housing.

Strategic Plan (§ 91.415)

This section of the consolidated plan regulations describes the prescribed content of a consortia's strategic plan. This section requires a consortia to comply with the provisions of § 91.215, which is proposed to be revised by this rule to incorporate the AFH in the strategic plan. The change that would be made to § 91.415 by this rule is to require the consortia to set forth, in its strategic plan, strategies and actions consistent with the goals and other elements identified in an AFH conducted in accordance with new § 5.154.

Action Plan (§ 91.420)

This section of the consolidated plan regulations describes the prescribed content of a consortia's action plan. Paragraph (b) of § 91.420 is revised to provide that the action plan must include actions that the consortia plans to take during the next year that will address fair housing issues identified in the consortia's AFH.

Certifications (§ 91.425)

As with the amendments to §§ 9.225 and 91.325, the proposed rule would amend paragraph (a)(1) of this section to provide that the consortia's certification that it will affirmatively further fair housing means that the consortia will take meaningful actions to further the goals identified in the AFH conducted in accordance with the requirements of 24 CFR 5.154, and that it will take no action that is materially inconsistent with its obligation to affirmatively further fair housing.

Amendments to the Consolidated Plan (§ 91.505)

This section lists the criteria and procedures by which a jurisdiction must amend its approved consolidated plan. The proposed rule adds a new paragraph (d) to this section that requires a jurisdiction to ensure that amendments to the plan are consistent with its certification to affirmatively further fair housing and the analysis and strategies of the AFH.

HOME Investment Partnerships (HOME) Program Regulations

Submission of a Consolidated Plan and Assessment of Fair Housing (§ 92.104)

This section of the HOME program regulations which addresses the responsibility of a participating jurisdiction to submit its consolidated plan to HUD is revised to provide that the jurisdiction must also submit its AFH to HUD, in accordance with the AFFH regulations in 24 CFR part 5, subpart A.

Recordkeeping (§ 92.508)

The proposed rule would amend the recordkeeping requirements of the HOME program to provide in paragraph (a)(7)(i)(C) of this section to require as part of the documentation that the participating jurisdiction has taken actions to affirmatively further fair housing, documentation of the participating jurisdiction's AFH.

Community Development Block Grant (CDBG) Regulations (24 CFR Part 570)

Definitions (§ 570.3)

Section 570.3, the definition section of HUD's CDBG regulations, would be revised to reflect that the terms ''*Affirmatively Furthering Fair Housing,*'' and ''*Assessment of Fair Housing or AFH*'' are defined in 24 CFR part 5.

Eligible Planning, Urban Environmental Design, and Policy Planning Management—Capacity Building Activities (§ 570.205)

This section which lists policy planning and capacity building activities would replace, in paragraph (a)(4)(vii), the reference to the AI with the AFH.

Citizen Participation—Insular Areas (§ 570.441)

This section would be revised to provide that a citizen participation plan is also applicable to the AFH.

General (§ 570.480)

Paragraph (c) of this section, which addresses HUD's review of state performance under the CDBG program, is revised to provide that such review includes review of the state's responsibility to affirmatively further fair housing.

Local Government Requirements (§ 570.486)

Paragraphs (a)(2), (a)(4), and (a)(5) of this section would be revised to reflect that the local government requirements addressed by these paragraphs include requirements necessary for effective assessment of fair housing.

Other Applicable Laws and Related Program Requirements (§ 570.487)

Paragraph (b) of this section, which addresses affirmatively furthering fair housing, provides that a state assumes responsibility for fair housing planning by taking meaningful actions to further the goals identified in an AFH undertaken in accordance with the

requirements of 24 CFR 5.154; and by not taking actions that are materially inconsistent with the state's obligation to affirmatively further fair housing.

Recordkeeping Requirements (§ 570.490)

Paragraph (a) of this section would be amended to provide that documentation of the state's AFH is one of the records that a state must maintain as part of its records supporting its administration of CDBG funds.

Records To Be Maintained (§ 570.506)

Similar to the amendment to § 570.490, the proposed rule would amend this section to provide in paragraph (g)(1) that documentation related to the recipient's AFH is part of the fair housing and equal opportunity records that a recipient is required to maintain.

Public Law 88–352 and Public Law 90–284; Affirmative Furthering Fair Housing: Executive Order 11063 (§ 570.601)

Paragraph (a)(2) of this section is amended to provide that the program participant's responsibility to undertake fair housing planning includes taking meaningful actions to further the goals identified in an AFH that is undertaken in accordance with the requirements of 24 CFR 5.154 and not taking actions that are materially inconsistent with its obligation to affirmatively further fair housing.

Equal Opportunity and Fair Housing Review Criteria (§ 570.904)

Paragraph (c) of this section is revised to provide that the review criteria for compliance with fair housing requirements includes review of a recipient's performance related to its responsibility to affirmatively further fair housing.

Housing Opportunities for Persons With AIDS (HOPWA) (24 CFR Part 574)

Recordkeeping (§ 574.530)

The proposed rule would amend this section of the HOPWA regulations to include documentation of a program participant's AFH as records that must be maintained for a period of 4 years.

Emergency Solutions Grants Program (ESG) (24 CFR Part 576)

Recordkeeping and Reporting Requirements (§ 576.500)

The proposed rule would amend paragraph (s) of this section to provide that documentation related to its AFH is additional documentation that an ESG recipient must maintain.

Public Housing Agency Plans (24 CFR Part 903)

What a PHA Must Do To Deconcentrate Poverty in Its Developments and Comply With Fair Housing Requirements (§ 903.2)

The proposed rule would amend § 903.2 by adding paragraph (a)(3), providing that for a PHA's development related activities, including affirmative marketing; tenant selection and assignment policies; applicant consultation and information; provision of additional supportive services and amenities; as well as construction, conversion, rehabilitation, modernization, demolition, disposition, designation, or physical accessibility of its housing and other facilities under its PHA Plan, should be designed to reduce racially or ethnically concentrated areas of poverty, reduce segregation and promote integration, reduce disparities in access to community assets, and address disproportionate housing needs by protected class.

The proposed rule similarly would amend section (d) to specify that PHA policies that govern eligibility, selection, and admissions under its PHA Plan must be designed to reduce the concentration of tenants and other assisted persons by race, national origin, and disability in conformity with the applicable AFH. Moreover, any PHA plans for the construction, conversion, rehabilitation, modernization, demolition, disposition, designation, or physical accessibility of its housing and other facilities must be consistent with the applicable AFH.

Information Provided in the Annual Plan (§ 903.7)

The proposed rule would revise § 903.7, paragraph (o), to indicate that each PHA must certify, among other things, that it will affirmatively further fair housing, which means that it will take meaningful actions to further the goals identified in the AFH conducted in accordance with the requirements of 24 CFR 5.154, and that it will take no action that is materially inconsistent with its obligation to affirmatively further fair housing.

Relations of PHA Plan to Consolidated Plan (§ 903.15)

The proposed rule would revise § 903.15 in paragraph (a) to indicate that an AFH is required for the PHA Plan in accordance with 24 CFR part 5, subpart A, but that PHAs may take one of three approaches in meeting this requirement, as appropriate.

First, the PHA may participate with the relevant unit of general local government in developing an AFH together. For this option, the PHA will work with the local government where 60 percent of the PHA's projects (i.e., hard units only) are located; however, if the majority is closer to 50 percent, the PHA may choose the local government that more closely aligns to its planning activities. For PHAs with only Section 8 tenant-based assistance, the PHA will coordinate with the jurisdiction that governs the PHA's operations (e.g., where the Mayor appoints the Board that hires the Executive Director). If the PHA disagrees with any aspect of the AFH, it may submit a dissenting statement or submission of alternative views, which will become part of the AFH and be reviewed through the same process as the AFH. HUD may then accept the entire AFH or either portion of the AFH representing the views of the unit of general local government or the PHA.

The second option is that the PHA conduct its own AFH with geographic scope and proposed actions scaled to the PHA's operations. Finally, as a third option, for PHAs that are covered by a state agency, the PHA may participate with the state in the preparation of the state agency's AFH but would be bound either way by the state agency conclusions contained in the state's AFH.

Paragraphs (b) and (c) would provide that a PHA may request to change its fiscal year to better coordinate its planning with the planning done under the consolidated plan process, by the state or local officials, as applicable. If the PHA selects the second option, it must update its own AFH every year.

Paragraph (d) would indicate that binding agreements such as a Recovery Agreement or Voluntary Compliance Agreement may incorporate the corrective actions that would require alternative AFH procedures, such as requiring that the PHA participate in its local jurisdiction's AFH.

Paragraph (e) would indicate that if a significant change necessitates a PHA Plan amendment, the PHA will have up to 18 months to make this change to its PHA Plan in accordance with the provisions of § 903.21.

Process for Reviewing Annual Plan (§ 903.23)

Finally, the proposed rule would add a new paragraph (f) to § 903.23 to require PHAs to maintain a copy of the AFH and records reflecting actions to affirmatively further fair housing as described in § 903.7(o).

IV. Questions for Commenters

HUD welcomes comments on all aspects of the proposal. In addition, HUD specifically requests comment on the following issues:

1. The field of geo-coded data is rapidly evolving and, as HUD works to refine data related to access important community assets, it welcomes suggestions for improvement. Such comments can include the description of cases or situations where the indicators may or may not appropriately portray neighborhood qualities. Are the nationally uniform data that HUD is providing to assist in the assessment of segregation, concentration of poverty, and disparities in access to community assets appropriate? Do these data effectively measure differences in access to community assets for each protected class, such as people with disabilities? To what extent, if at all, should local data, for example on public safety, food deserts, or PHA-related information, be required to supplement this nationally uniform local and regional data?

2. HUD requests comment on how the goals and priorities arising out of the AFH would influence local regulations, siting decisions, infrastructure investments, and policies, in comparison to the existing processes using the AI.

3. To what extent would the AFH and related public engagement and planning processes increase or decrease paperwork costs for program participants?

4. What experiences do HUD program participants have with the policy interventions considered in the Regulatory Impact Analysis (RIA) (please see full RIA at *www.regulations.gov* under the docket number 5173–P–01–RIA). What outcomes were observed? What data is available related to those outcomes?

5. Are there nonfinancial incentives that HUD should consider to encourage regional collaboration among local governments and states and greater engagement with public housing planning; for example, bonus points in specific grant programs? HUD welcomes comments about other potential incentives as well.

6. In terms of the cooperation of consolidated plan jurisdictions and PHAs, what are the best models and approaches and other considerations to facilitate that joint participation? What is the best method for consolidated plan program participants to use to begin their engagement with PHAs in the AFH process? Would a letter or other similar solicitation of involvement be sufficient?

7. In this regard, the proposed rule acknowledges that the 5-year planning cycles and program/fiscal years for PHAs and consolidated plan program participants might differ. While PHAs can adjust their 5-year planning cycles to more closely coincide with consolidated plan program participant planning cycles simply by submitting the 5-year plan early (e.g., after 3 years instead of 5), it is more difficult to adjust program/fiscal year ends. The AFH is an important input for the consolidated plan and the PHA Plan, and it should be conducted before the PHA and consolidated plan program participant cycles begin. What would be the best way to accomplish this?

8. Are there other planning efforts (for example, in transportation, education, health, and other areas) or other federal programs, such as the low income housing tax credit, that should be coordinated with the fair housing planning effort contemplated by this rule, and, if so, how and what issues would be best informed by this coordination? In recognition of the interdependent nature of how communities develop and what influences community progress related to the goals set forth in this rule, what are the appropriate scope of activities that should be considered ''activities relating to housing and urban development'' under the Fair Housing Act for purposes of this rule?

9. An analysis of disproportionate housing needs is currently required as part of the consolidated plan, and this proposed rule would make disproportionate housing needs an element of the AFH as well. If a disproportionate housing needs analysis is a part of the AFH, should it remain in the consolidated plan as well? Is this analysis most appropriate in either the AFH or the consolidated plan, or is it appropriate, as the current proposed rule contemplates, to have the analysis in both places, assuming the analysis is the same for both planning exercises?

10. Are there appropriate indicators of effectiveness that should be used to assess how program participants have acted with regard to the goals that are set out?

11. What forms of technical assistance would be most useful to program participants in undertaking the AFH called for in the proposed rule?

12. Are there any requirements of the new structure that the proposed rule will create that should be modified for states?

13. Are there any requirements of the new structure that the proposed rule will create that should be modified for small program participants, such as small units of local general government and small PHAs?

14. Are there aspects of incorporation of the new AFH community participation and consultation process into analogous aspects of the existing consolidated plan process that could be improved? For example, is 15 days sufficient now for public comment on consolidated plan program participants' annual performance report under 24 CFR 91.105(d)?

15. What length of time (such as 12, 18, or 24 months) is needed for PHAs to revise their PHA Plans to address AFH recommendations?

16. If the AFH is not acceptable after the back-and-forth engagement provided for in § 5.162 of the proposed rule because of disagreements between program participants collaborating on an AFH, what process should guide the resolution of disputes between program participants?

17. Should there be an end date for the technical assistance and back-and-forth engagement provided for in § 5.162 if a portion of an AFH that involves multiple program participants can be accepted, thus allowing an individual program participant to be accepted?

18. For program participants that have recently conducted a comprehensive AI, should HUD waive or delay implementation of the AFH requirement for those program participants?

19. Section 5.164 of the proposed rule recognizes that events outside the control of a program participant may require revising the AFH during the course of a 5-year planning cycle. This is especially true in the case of a significant natural disaster, although the rule contemplates other similar material changes in circumstances that might likewise require revising the AFH. What process and challenges will a program participant face when an unexpected occurrence, such as a natural disaster, dictates that it take actions that may be contrary to its applicable plan contents? What impact might a natural disaster or similar type of occurrence have on a program participant's compliance with the AFH?

V. Findings and Certifications

Regulatory Planning and Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory

Review) directs executive agencies to analyze regulations that are outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. This rule was determined to be a ''significant regulatory action,'' as defined in section 3(f) of Executive Order 12866 (although not an economically significant regulatory action under the order). HUD submits that the approach to fair housing planning proposed by this rule is consistent with the objectives of Executive Order 13563 to reduce burden, as well as the goal of modifying and streamlining regulations that are outmoded and ineffective. HUD completed a Regulatory Impact Analysis for this proposal, which can be found at *www.regulations.gov*, under the docket number 5173–P–01–RIA. This section summarizes the findings of that analysis.

Summary of the Regulatory Impact Analysis

This rule proposes to establish a regulatory framework for affirmatively furthering fair housing, as required by the Fair Housing Act. In accordance with the Fair Housing Act, program participants are required to use HUD funds in a manner that affirmatively furthers fair housing. In addition, these program participants have an independent statutory obligation to affirmatively further fair housing under several statutes. While to date, HUD has accepted, consistent with statutory requirements, a certification from these program participants that the program participant will affirmatively further fair housing, HUD has found, at times, that a program participant is either not affirmatively furthering fair housing or the program participant's affirmatively furthering fair housing strategy is inadequate.

Through this rule, HUD proposes to provide recipients of HUD funds with more information to assist them in fulfilling the charge to affirmatively further fair housing. This proposed rule is needed for two reasons: to overcome barriers to fair housing choice and to encourage improvements in the current planning process.

This rule is needed to facilitate efforts to overcome barriers to fair housing choice. There are many different types of impediments to fair housing choice, including building and zoning codes, processes for site selection for low-income housing, lack of public services in low-income areas, less favorable mortgage lending for minority borrowers, and lack of public awareness of rights and responsibilities associated with fair housing. Some of these impediments may prevent people from moving out of racially concentrated areas of poverty and neighborhoods that perpetuate disparities in access to community assets. Other factors may prevent these neighborhoods from attracting a sufficiently broad distribution of people such that segregation and racial concentration of poverty dissipate over time. One purpose of this rule is to help program participants identify and alleviate these barriers to equality in access to important community assets.

A second reason that the proposed rule is needed is because some of the traditional means of fair housing planning have not been as effective as they could be and can be updated with currently available information and approaches. Recipients of HUD grant funding can be assisted with better tools to understand patterns of segregation, racial and ethnic concentrations of poverty, disparities in access to community assets by protected class, and disproportionate housing needs based on protected class so that such program participants can better develop strategies, plans, and actions to address these fair housing concerns. The need for a revision of the current planning process was recognized by the GAO Report, which recommended the establishment of rigorous standards for AIs, regular submission of AIs, checking and verifying AIs, and measuring grantees' progress in addressing identified impediments to fair housing.

Intended to help program participants overcome these barriers and encourage improvements in planning, this rule proposes a ''fair housing assessment'' and planning process that will aid HUD program participants in improving access to community assets and housing of their residents. HUD will provide states, local governments, PHAs, and the communities they serve with local and regional data on patterns of integration, racially and ethnically concentrated areas of poverty, access to community assets in select domains, and disproportionate housing needs based on protected class. From these data, program participants would be required to evaluate their present environment to assess fair housing issues, identify the primary determinants that account for those issues, and set forth fair housing priorities and goals and document these activities in an AFH report. The rule also proposes new procedures within HUD for evaluating grantees' fulfillment of their obligation to affirmatively further fair housing. While the change in compliance costs of the rule is expected to be small, the vast array of choices and strategies open to grantees make it difficult to be quantitatively precise beyond a qualitative description of the total and net benefits.

HUD does not expect a large change in compliance cost as a result of the rule, as states, local governments, and PHAs are already required to prepare analyses of impediments to fair housing choice, undertake activities to overcome such barriers, and maintain records of the activities and their impact. HUD estimates a marginal compliance cost impact of between $3 million to $9 million compared to existing requirements, arising from new proposed features, the primary of these being program participants formally submitting the AFH to HUD for review and feedback; the more precise definition of the contents of the AFH as compared to existing AI requirements; HUD's provision of data for further analysis; and a more precisely defined community participation process. Further, HUD anticipates a reallocation of staff resources towards AFFH-related tasks, resulting in a notional internal transfer of funds towards AFFH.

Regarding quantifiable benefits, the AFFH proposed rule is designed to help provide information and perspectives on fair housing issues to jurisdictions in a manner that is clearer and easier to elucidate. The goal is that the information, standards concerning the formulation of the AFH, and improved accountability will improve fair housing outcomes and thus the welfare of members of the protected classes and their communities. However, it is difficult to predict in order to quantify for the purposes of assessing regulatory impact exactly how a program participant will use the information, what decisions they will reach, and precisely how those decisions will affect members of protected classes. The AFFH process is only one factor that determines what actions are pursued and what impacts are ultimately achieved. At every step in the policy-making process there are uncertainties that have implications for both the types and size of effects that the rule may have.

First, the ultimate effect of the rule will depend upon the policy preferences of individual program participants, including whether it is favorably predisposed toward fair housing

policies, the character of the local bureaucracy, and whether the limited incentives of the rule will affect the program participant's active engagement in its fair housing obligations. There is a multitude of perspectives that can drive resident and, by extension, jurisdictional preferences, which makes predicting jurisdictional preferences difficult.

A second issue is whether the information emerging from the proposed process will be new for the jurisdiction. In some, but not all cases, the information will be new and shed light on issues that had not previously been emphasized, but which could now be understood to be important. In these instances, program participants might highlight additional goals or supplant existing goals with goals that are more effective and pertinent for fair housing outcomes. Importantly, the new goals could be of primary or secondary significance from a strategic perspective and compared to other competing legitimate public policy concerns, which has implications for the policies that are ultimately considered.

Even with information about the general course of action a program participant will take, it remains difficult to predict the exact policy choices that the program participant will make. There are typically many policy options for addressing a particular concern, such as the availability of affordable housing or public transportation, and the proposed rule does not prescribe or enforce specific local or PHA policies. Instead, it allows for a flexible approach that is appropriate to local needs and housing market conditions and recognizes that available resources may represent a constraint. Which among the various policy options is selected by a program participant will depend fundamentally on the local context and the particular circumstances that prevail when the issues are considered.

Despite the uncertainty regarding the precise actions that program participants might settle upon, it is possible to characterize the actions that program participants are likely to pursue. These can be grouped into four general categories, each defined by what they seek to accomplish in the local jurisdiction or by the relevant PHA, as appropriate. These categories are modifying local regulations and codes, constructing new developments, creating new amenities, and facilitating the movement of people. Each category features a large set of policy alternatives. After identifying fair housing issues and their root causes, prioritizing among them, and concluding which activities would be best to pursue, program participants will consider these alternatives and decide which, if any, should be included in subsequent plans and implemented. For each class of activities, the Regulatory Impact Analysis offers examples of how this process might play out for program participants.

Finally, in terms of quantifying the effects of the proposed rule, there is uncertainty about the potential impacts of whichever policy is selected by a program participant. For example, inclusionary zoning policies—one potential action that jurisdictions might take in this context—have been implemented by a number of communities across the country, often for the purpose of advancing fair housing goals. Research assessing these efforts is mixed, with some studies suggesting they increase prices and decrease housing stock in the long run, some studies showing they have no effect, and other studies indicating they increase the supply of multifamily housing units. For this example, as well as the other policies program participants might consider in the course of their AFFH planning process, the impact will depend on a complex interaction of a broad set of judgments and decisions by the jurisdiction, other jurisdictions, private and non-profit actors, and families, both in protected classes and not. These can differ across regions and families in ways that are impossible to predict in advance. Accordingly, impacts will be revealed in the months and years following policy implementation.

In brief, the proposed rule presents an improved process for carrying out the statutory AFFH mandate, resulting in the potential to improve the lives of people in protected classes who are denied fair housing choice by barriers to such choice. The best outcome of the rule would be for each jurisdiction to not only undertake meaningful fair housing planning, but also to have capacity and a well-considered strategy to implement actions to affirmatively further fair housing. However, the specific actions of a local government or PHA that would generate benefits for protected classes are not prescribed, obligated, or enforced by the proposed rule. Instead, the rule encourages a more engaged and data-driven approach to assessing the state of fair housing and planning actions to affirmatively further fair housing than before.

Considering the overall impact of the proposed rule, estimates suggest the proposed rule will have relatively limited additional paperwork and planning costs. Program participants already are required to engage in outreach and collect data in order to satisfy existing obligations, and HUD is reducing significant data burdens. While some additional outreach costs are possible, they are expected to be relatively small. Thus, compliance costs of the proposed rule are expected to be comparable to those under the current regime.

In terms of quantifying the community impacts of the proposed rule, this analysis has highlighted the uncertainty that exists regarding how the new information generated through the new AFH process will translate into different actions by program participants. In terms of estimating impact, this suggests that the probability that any particular outcome occurs is exceedingly small. Moreover, the analysis has identified uncertainty with respect to how much specific actions will advance fair housing goals.

However, any different actions that are taken by program participants are likely to represent new local and PHA approaches to reducing segregation, eliminating racially concentrated areas of poverty, reducing disparities in access to community assets, and addressing disproportionate housing needs by protected class. HUD is confident that some of these new approaches will be more successful in achieving the goals of fair housing, meaning that communities will be more integrated, fewer people will live in neighborhoods with both high poverty rates and high racial concentrations, and there will be fewer and smaller disparities in access to quality education, job opportunities, and other community assets.

Environmental Impact

This proposed rule is a policy document that sets out fair housing and nondiscrimination standards. Accordingly, under 24 CFR 50.19(c)(3), this proposed rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*).

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The undersigned certifies that this rule would not have a significant economic impact on a substantial number of small entities.

This rule proposes to strengthen the way in which HUD and its program participants meet the requirement under the Fair Housing Act to take affirmative steps to further fair housing. The preamble identifies the statutes and executive orders that address this requirement and that place responsibility directly on certain HUD program participants, specifically, local governments, states, and PHAs, underscoring that the use of federal funds must promote housing choice and open communities. Although local governments, states, and PHAs must affirmatively further fair housing independent of any regulatory requirement imposed by HUD, HUD recognizes its responsibility to provide leadership and direction in this area, while preserving local determination of fair housing needs and strategies.

This rule primarily focuses on establishing a regulatory framework by which program participants may more effectively meet their statutory obligation to affirmatively further fair housing. The statutory obligation to affirmatively further fair housing applies to all program participants, large and small. The statutory obligation requires program participants to develop strategies to affirmatively further fair housing as part of statutorily imposed plans that address the use of HUD funds and that must be submitted to HUD for review and approval. This rule builds on the statutory requirements to affirmatively further fair housing in conjunction with the development of consolidated plans for state and local governments, and PHA Plans for PHAs and, in doing so, provides for all program participants to comply with their statutory requirements in a cost-efficient, but also effective manner.

The current statutory requirement imposed on states, local governments, and PHAs requires the program participant to certify that it is affirmatively furthering fair housing. While that certification is a simple and brief document to submit to HUD, it nevertheless represents the attestation of the program participant that it will take steps to affirmatively further fair housing. While the certification is an important component of a program participant's statutory obligation to affirmatively further fair housing, even more important is the specific actions that the program participant plans to take to affirmatively further fair housing. Because the Fair Housing Act requires that HUD programs and activities be administered in a manner that affirmatively furthers the policies of the Fair Housing Act, it is important for HUD to review the plans that will guide the activities jurisdictions will undertake so that the Secretary can be assured that HUD program participants are in fact affirmatively furthering fair housing. The rule, therefore, provides for program participants to submit an AFH to HUD.

The rule proposes to reduce the administrative burden on program participants in preparing and submitting an AFH to HUD as compared to the current AI process by HUD providing fair housing related data. HUD will provide program participants with local and regional data on access to community assets through categories such as education, employment, low-poverty exposure, and transportation, as well as patterns of integration and segregation, racial and ethnic concentrations of poverty, and disproportionate housing needs based on protected class, and data on national trends in housing discrimination. With this data, program participants can perform an in-depth evaluation for their area of patterns of integration and segregation, disparities in access to community assets by members of protected classes, racial and ethnic concentrations of poverty, and disproportionate housing needs based on protected class; identify the areas for improvement revealed by this data; and develop the tools, strategies, and priorities that program participants intend to deploy in these areas to respond to these patterns. HUD will also be available to provide technical assistance to program participants in the development of their AFHs. It is HUD's position that this provision of data by HUD and HUD's more active role in assisting program participants with an AFH will reduce burden for all program participants large and small, in meeting their statutory obligation to affirmatively further fair housing.

Nevertheless, HUD is sensitive to the fact that the uniform application of requirements on entities of differing sizes often places a disproportionate burden on small entities.

Specific solicitation of comment. HUD, therefore, is soliciting alternatives for compliance from small entities as to how these small entities might comply in a way less burdensome to them.

Executive Order 12612, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on state and local governments and is not required by statute, or preempts state law, unless the relevant requirements of section 6 of the executive order are met. This rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the executive order.

The proposed rule will assist program participants of HUD funds to satisfactorily fulfill the statutory AFFH obligation. As HUD has noted in the preceding section discussing the Regulatory Flexibility Act, and in the Background section of this preamble, the obligation to affirmatively further fair housing is imposed by statute directly on local governments, states, and PHAs. As the agency charged with administering the Fair Housing Act, HUD is responsible for overseeing that its programs are administered in a manner that further purposes and policies of the fair housing and entities receiving HUD funds fulfill their affirmatively furthering fair housing obligation.

The approach taken by HUD in this rule is to help local governments, states, and PHAs meet this obligation in a way that is meaningful, but without undue burden. As noted throughout this preamble, HUD proposes to provide local and regional data on patterns of integration and segregation and access to community assets in education, neighborhood stability, credit, employment, transportation, health, and other community amenities, as well as national trends in housing discrimination. This approach, in which HUD offers data, clear standards, guidance, and technical assistance, is anticipated to reduce burden and costs that is involved in current regulatory schemes governing affirmatively furthering fair housing. Since federal law requires states and local governments to affirmatively further fair housing, there is no preemption, by this rule, of state law.

Paperwork Reduction Act

The information collection requirements contained in this proposed rule have been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number.

HUD anticipates that the impact of this rule on document preparation time

is reduced from the burden that it may otherwise be because the rule integrates the AFH with the consolidated and PHA planning processes. Additionally, states, local governments, and PHAs are required already to undertake an AI, prepare written AFFH plans, undertake activities to overcome identified barriers to fair housing choice, and maintain records of the activities and their impact. The principal differences imposed by the proposed rule are that program participants would submit the plan to HUD for review and feedback, the contents of the plan would be more defined, HUD would provide data for further analysis, and there would be a more defined community participation process. Because the fair housing planning process is tied to existing consolidated plan and PHA Plan processes, local governments, states, and PHAs would not have to establish wholly new procedures.

The burden of the information collections in this proposed rule is estimated as follows:

REPORTING AND RECORDKEEPING BURDEN

Section reference	Number of parties	Number of responses per respondent	Estimated average time for requirement (in hours)	Estimated annual burden (in hours)
§ 5.154 (Assessment of Fair Housing) & § 5.158 (AFH Submission Requirements including Recordkeeping), including § 5.158 (Community participation and consultation); § 91.100 (ConPlan Consultation; local governments, requirements specific for AFH); § 91.105 (ConPlan Citizen participation plan, requirements specific for AFH); § 92.104 (HOME Program—Submission of the AFH); § 570.441 (CDBG—Inclusion of AFH in citizen participation plan for insular areas) and § 903.15 (PHA Plan—Options for meeting requirements to prepare AFH) [This reporting requirement consolidates the recipients and burden hours for the consolidated plan jurisdictions (1,150), and PHAs (3,400), and builds on the response time and burden hours specified for preparation and submission of the consolidated plan, and PHA Annual Plan, respectively.]	4,550	1	200.00	910,000.00
§ 5.156 (Regional AFHs) [This information collection requirement contemplates that perhaps a third of the 4071 PHAs will initially partner with jurisdictions to prepare a Regional AFH.]	1,542	1	100.00	154,200.00
§ 5.164 (Revising the AFH) [This information collection requirement contemplates that perhaps a quarter of all respondents may have to, at any given point, be required to revise the AFH.]	1,000	1	50.00	50,000.00
§ 91.215 (Local Government—Strategic plan, requirements specific for AFH)	1,000	1	270.00	270,000.00
§ 91.220 (Local Government—Action plan, requirements specific for AFH)	1,000	1	150.00	150,500.00
§ 91.315 (States—Strategic plan, requirements specific for AFH)	50	1	700.00	35,000.00
§ 91.320 (States—Action plan, requirements specific for AFH)	50	1	450.00	22,500.00
§ 91.415 (Consortia—Strategic plan, requirements specific for AFH)	150	1	200.00	30,000.00
§ 91.420 (Consortia—Action plan, requirements specific for AFH)	150	1	100	15,000.00
Total Burden				1,637,200.00

In accordance with 5 CFR 1320.8(d)(1), HUD is soliciting comments from members of the public and affected agencies concerning this collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology; e.g., permitting electronic submission of responses.

Interested persons are invited to submit comments regarding the information collection requirements in this rule. Under the provisions of 5 CFR part 1320, OMB is required to make a decision concerning this collection of information between 30 and 60 days after today's publication date. Therefore, a comment on the information collection requirements is best assured of having its full effect if OMB receives the comment within 30 days of today's publication. This time frame does not affect the deadline for comments to the agency on the proposed rule, however. Comments must refer to the proposal by name and docket number (FR–5173) and must be sent to:

HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503, Fax number: (202) 395–6947, and

Colette Pollard, Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street SW., Room 2204, Washington, DC 20410.

Interested persons may submit comments regarding the information collection requirements electronically through the Federal eRulemaking Portal at *http://www.regulations.gov*. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

List of Subjects

24 CFR Part 5

Administrative practice and procedure, Aged, Claims, Grant

programs-housing and community development, Individuals with disabilities, Intergovernmental relations, Loan programs-housing and community development, Low and moderate income housing, Mortgage insurance, Penalties, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

24 CFR Part 91

Aged, Grant programs—housing and community development, Homeless, Individuals with disabilities, Low and moderate income housing, Reporting and recordkeeping requirements.

24 CFR Part 92

Administrative practice and procedure, Grant programs-housing and community development, Low and moderate income housing, Manufactured homes, Rent subsidies, and Reporting and recordkeeping requirements.

24 CFR Part 570

Administrative practice and procedure, American Samoa, Community development block grants, Grant programs—education, Grant programs—housing and community development, Guam, Indians, Lead poisoning, Loan programs—housing and community development, Low and moderate income housing, New communities, Northern Mariana Islands, Pacific Islands Trust Territory, Pockets of poverty, Puerto Rico, Reporting and recordkeeping requirements, Small cities, Student aid, Virgin Islands.

24 CFR Part 574

Community facilities, Disabled, Grant programs—health programs, Grant programs—housing and community development, Grant programs—social programs, HIV/AIDS, Homeless, Housing, Low and moderate income housing, Nonprofit organizations, Rent subsidies, Reporting and recordkeeping requirements, Technical assistance.

24 CFR Part 576

Community facilities, Emergency solutions grants, Grant programs—housing and community development, Grant program—social programs, Homeless, Reporting and recordkeeping requirements.

24 CFR Part 903

Administrative practice and procedure, Public housing, Reporting and recordkeeping requirements.

Accordingly, for the reasons described in the preamble, HUD proposes to amend parts 5, 91, 92, 570, 574, 576, and 903 of title 24 of the Code of Federal Regulations as follows:

PART 5—GENERAL HUD PROGRAM REQUIREMENTS; WAIVERS

Subpart A—Generally Applicable Definitions and Federal Requirements; Waivers

■ 1. The authority citation for part 5, subpart A, is revised to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437c–1(d), 1437d, 1437f, 1437n, 3535(d), and Sec. 327, Pub.L. 109–115, 119 Stat. 2936; 42 U.S.C. 3600–3620; 42 U.S.C. 5304(b); 42 U.S.C. 12704–12708; E.O. 11063, 27 FR 11527, 3 CFR, 1958–1963 Comp., p. 652; E.O. 12892, 59 FR 2939, 3 CFR, 1994 Comp., p. 849.

■ 2. Subpart A is amended to by adding §§ 5.150–5.180 under the undesignated heading of ''Affirmatively Furthering Fair Housing'' to read as follows:

* * * * *

Affirmatively Furthering Fair Housing

Sec.

Affirmatively Furthering Fair Housing

§ 5.150 Affirmatively Furthering Fair Housing: purpose.

The purpose of the Affirmatively Furthering Fair Housing (AFFH) regulations in §§ 5.150–5.180 is to improve fair housing choice for all through fair housing planning, strategies, and actions. The regulatory framework does this by providing clearer standards, greater technical assistance from HUD, and a stronger accountability system governing fair housing planning, strategies, and actions. In furtherance of the statutory obligation to affirmatively further fair housing under the Fair Housing Act; Title VIII of the Civil Rights Act of 1968; as well as, as applicable, the Housing and Community Development Act of 1974, the Cranston-Gonzalez National Affordable Housing Act, and the Housing Act of 1937, the regulations establish the specific requirements for the development and submission of an Assessment of Fair Housing (AFH) by program participants (including local governments, states, and public housing agencies (PHAs)), and the incorporation of that AFH into subsequent consolidated plans and PHA Plans. In this way, the AFFH regulatory framework provides program participants a way to assess issues related to fair housing choice and identify fair housing goals that will inform housing and community development policy and investment planning. A program participant's strategies and actions may include strategically enhancing neighborhood assets (e.g., through targeted investment in neighborhood revitalization or stabilization) or promoting greater mobility and access to areas offering vital assets such as quality schools, employment, and transportation, consistent with fair housing goals.

§ 5.152 Definitions.

For purposes of this subpart, the terms ''*consolidated plan*'', ''*consortium*'', ''*unit of general local government*'', ''*jurisdiction*'', and ''*state*'' are defined in 24 CFR part 91. The following additional definitions are provided for this subpart:

Affirmatively furthering fair housing means taking proactive steps beyond simply combating discrimination to foster more inclusive communities and access to community assets for all persons protected by the Fair Housing Act. More specifically, it means taking steps proactively to address significant disparities in access to community assets, to overcome segregated living patterns and support and promote integrated communities, to end racially and ethnically concentrated areas of poverty, and to foster and maintain compliance with civil rights and fair housing laws. For participants subject to this subpart, these ends will be accomplished primarily by making investments with federal and other resources, instituting strategies, or taking other actions that address or mitigate fair housing issues identified in an assessment of fair housing (AFH) and promoting fair housing choice for all consistent with the policies of the Fair Housing Act.

Assessment of Fair Housing (assessment or AFH) means the document that is submitted to HUD pursuant to § 5.154 that includes fair housing data analysis, an assessment of fair housing issues and determinants, and an identification of fair housing priorities and general goals.

Assessment tool. See definition of ''*Instructions*'' below.

Community participation means a solicitation of views and recommendations from the public (including citizens, residents, and other interested parties), a consideration of

the views and recommendations received, and a process for incorporating such views in decisions and outcomes.

Consolidated plan program participant means any entity specified in § 5.154(b)(1).

Disproportionate housing needs exists when the percentage of extremely low-income, low-income, moderate-income, and middle-income families in a category of housing need who are members of a protected class is at least 10 percent higher than the percentage of persons in the category as a whole. For this purpose, categories of housing need are cost burden and severe cost burden, overcrowding (especially for large families) and substandard housing conditions. The terms cost burden, severe cost burden, overcrowding, extremely low-income family, low-income family, moderate-income family, and middle-income family are defined in 24 CFR 91.5.

Fair housing choice means that individuals and families have the information, options, and protection to live where they choose without unlawful discrimination and other barriers related to race, color, religion, sex, familial status, national origin, or handicap. It encompasses actual choice, which means the existence of realistic housing options; protected choice, which means housing that can be accessed without discrimination; and enabled choice, which means the availability and realistic access to sufficient information regarding options so that any choice is informed. For persons with disabilities, fair housing choice includes access to accessible housing, and, for disabled persons in institutional or other residential environments, housing in the most integrated setting appropriate as required under law, including disability-related services that an individual needs to live in such housing.

Fair housing determinant means a factor that creates, contributes to, or perpetuates one or more fair housing issues.

Fair housing enforcement and fair housing outreach capacity means the ability of a jurisdiction, and organizations located in the jurisdiction, to accept complaints of violations of fair housing laws, investigate such complaints, obtain remedies, engage in fair housing testing, and educate community members about fair housing laws and rights and includes any state or local agency that enforces a law substantially equivalent to the Fair Housing Act (see 24 CFR part 115) and any organization participating in the Fair Housing Initiative Programs (see 24 CFR part 125).

Fair housing issue means ongoing local or regional segregation or the need to support integrated communities; racial or ethnic concentrations of poverty; disparities in access to community assets; disproportionate housing needs based on race, color, religion, sex, familial status, national origin, or handicap; and evidence of illegal discrimination or violations of existing civil rights law, regulations, or guidance, as well as any other condition that impedes or fails to advance fair housing choice.

Instructions and assessment tool refer to guidance that HUD will issue to program participants providing directions on how to use the data to be provided and the assessment to be conducted pursuant to § 5.154, and such guidance will be updated periodically as may be necessary.

Insular area means any of the following: Guam, the Northern Mariana Islands, the Virgin Islands, and American Samoa.

Integration means, based on the most recent decennial Census and other data sources as determined by HUD to be statistically valid, that particular geographic areas within a jurisdiction do not contain high concentrations of persons of a particular race, color, religion, sex, familial status, national origin, or handicap when compared to the jurisdiction or Metropolitan Statistical Area as a whole. For individuals with disabilities, integration also means that such individuals are housed in the most integrated setting appropriate. The most integrated setting is one that enables individuals with disabilities to interact with nondisabled persons to the fullest extent possible, consistent with the requirements of the Americans with Disabilities Act (42 U.S.C. 12101, *et seq.*), and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794). See 28 CFR, part 35, App. A (2010) (addressing 25 CFR 35.130).

Program participants means any entities specified in § 5.154(b).

Protected class means a class of persons who are protected from housing discrimination on the basis of race, color, religion, sex, familial status, national origin, or handicap under the Fair Housing Act.

Racially or ethnically concentrated area of poverty (RCAP or ECAP) means a geographic area based on the most recent decennial Census and other data sources as they are determined by HUD to be statistically valid, with significant concentrations of extreme poverty and minority populations.

Regionally collaborating program participants means those program participants collaborating to conduct a Regional AFH pursuant to § 5.156.

Segregation means geographic areas, based on the most recent decennial Census and other data sources determined by HUD to be statistically valid, with high concentrations of persons of a particular race, color, religion, sex, familial status, national origin, or with a disability in a particular housing development, or a jurisdiction, compared to the jurisdiction or Metropolitan Statistical Area, as a whole resulting from fair housing determinants or other causes. For persons with disabilities, segregation includes the failure to provide housing in the most integrated setting possible.

Significant disparities in access to community assets means measurable differences in access to educational, transportation, economic, and other important assets in a community based on housing unit location and race, color, religion, sex, familial status, national origin, or disability, based on the most recent decennial Census and other data sources determined by HUD to be statistically valid, program participant-provided supplemental or replacement data that has an empirical basis, or both.

§ 5.154 Assessment of Fair Housing (AFH).

(a) *General.* To effectively meet the statutory obligation to affirmatively further fair housing, an assessment of the elements and factors that cause or maintain disparity, segregation, and racially or ethnically concentrated areas of poverty is central to the development of a successful affirmatively furthering fair housing strategy (AFFH strategy). For HUD program participants already required to develop plans for effective uses of HUD funds consistent with the statutory requirements and goals governing such funds, an AFH will be integrated into such planning.

(b) *Requirement to submit AFH.* In furtherance of the statutory obligation to affirmatively further fair housing, an AFH must be developed and submitted in a manner and form prescribed by HUD by the following entities:

(1) Jurisdictions and Insular Areas that are required to submit consolidated plans for the following programs:

(i) The Community Development Block Grant (CDBG) programs (see 24 CFR part 570, subparts D and I);

(ii) The Emergency Solutions Grants (ESG) program (see 24 CFR part 576);

(iii) The HOME Investment Partnerships (HOME) program (see 24 CFR part 92); and

(iv) The Housing Opportunities for Persons With AIDS (HOPWA) program (see 24 CFR part 574).

(2) Public housing agencies (PHAs) receiving assistance under sections 8 and 9 of the United States Housing Act of 1937 (42 U.S.C. 1437f and 42 U.S.C. 1437g).

(3) Such other participants in HUD programs that may be subject to the AFFH regulations after [effective date of final rule] and announced by HUD through **Federal Register** notice.

(c) *Fair housing data provided by HUD.* HUD will provide program participants with nationally uniform local and regional data on patterns of integration and segregation; racially and ethnically concentrated areas of poverty; access to assets in education, employment, low-poverty, transportation, and environmental health, among others; disproportionate housing needs; data on individuals with disabilities and families with children; and data on discrimination. HUD will also provide PHA site locational data (including, to the extent available, accessible units), the distribution of housing choice vouchers, and occupancy data. Program participants shall use this information, in addition to any available local or regional information and information gained through community participation and consultation undertaken in accordance with § 5.158 to conduct an AFH.

(d) *Content.* In accordance with instructions prescribed by HUD, each program participant shall conduct an AFH for the purpose of identifying goals to affirmatively further fair housing and to inform fair housing strategies in the consolidated plan, the PHA Plan, other public housing related program plans such as Capital Fund Plans, community plans including, but not limited to, education, transportation, or environmental related plans. The AFH will address integration and segregation, concentrations of poverty, disparities in access to community assets, and disproportionate housing needs based on race, color, religion, sex, familial status, national origin, or handicap. In addition, the AFH will assess the jurisdiction's fair housing enforcement and fair housing outreach capacity. At a minimum, the AFH will include the following elements:

(1) *Summary of fair housing issues and capacity to address.* The AFH must include a summary of fair housing issues in the jurisdiction, including any findings or judgments related to fair housing or other civil rights laws and assessment of compliance with existing fair housing laws, regulations, and guidance, and an assessment of the jurisdiction's fair housing enforcement and fair housing outreach capacity.

(2) *Analysis of data.* Based upon HUD-provided fair housing data, available local or regional data, and community input, the analysis will:

(i) Identify integration and segregation patterns and trends across protected classes within the jurisdiction and region;

(ii) Identify racially or ethnically concentrated areas of poverty within the jurisdiction and region;

(iii) Identify whether significant disparities in access to community assets exist across protected classes within the jurisdiction and region; and

(iv) Identify whether disproportionate housing needs exist across protected classes within the jurisdiction and region.

(3) *Assessment of determinants of fair housing issues.* Using an assessment tool provided by HUD, the assessment will identify the primary determinants influencing conditions of integration and segregation, concentrations of poverty, disparities in access to community assets, and disproportionate housing needs based on protected class as identified under paragraph (d)(2) of this section.

(4) *Identification of fair housing priorities and general goals.* Consistent with the analysis and assessment conducted under paragraphs (d)(2) and (3) of this section, the AFH must:

(i) Identify and prioritize fair housing issues arising from the assessment and justify the chosen prioritization; and

(ii) Identify the most significant fair housing determinants related to these priority issues and set and prioritize one or more goal(s) for mitigating or addressing the determinants. The strategies or funding decisions subject to the consolidated plan, PHA Plan, or other relevant planning processes are not required to be detailed in an AFH.

(5) *Summary of community participation.* The AFH must include a concise summary of the community participation process, public comments, and efforts made to broaden community participation in the development of the assessment. A summary of the comments or views received in writing, or orally at public hearings, in preparing the final AFH, and a summary of any comments or views not accepted and the reasons why, must be attached to the final AFH.

(e) *Specific types of program participants*—(1) *PHAs.* If a PHA participating with the relevant consolidated plan program participant, pursuant to 24 CFR 903.15(a)(1), disagrees with any aspect of the AFH, including, but not limited to, assessments, strategies, or priorities, the PHA may submit to HUD and the unit of general local government a dissenting statement or submission of alternative views by the PHA's governing board or commission. The dissents and alternative views will become part of the AFH and will have the same deadline and review process as the AFH. In the case that all of the differentiated sections of the AFH are acceptable, the PHA and the consolidated plan program participant will be considered to have accepted the AFH. If a subset of the differentiated sections is not accepted, then the AFH for the PHA or the consolidated plan program participant associated with those sections will be considered not to be accepted. The determination of whether the AFH is accepted for the consolidated plan program participant, for the PHA or for both, is a determination to be made by HUD.

(2) *HOME program consortia.* This paragraph (e)(2) applies to HOME program consortia, as defined in 24 CFR 91.5 (see 24 CFR part 92). For purposes of the AFFH regulations, a HOME consortium is considered to be a single unit of general local government.

(i) *Home and CDBG consortia.* Units of local government that participate in a HOME consortium must participate in submission of an AFH for the consortium, prepared in accordance with this section. CDBG entitlement communities that are members of a consortium must provide such additional information as necessary for the consortium's AFH.

(ii) *Community participation.* The consortium must have a plan for community participation that complies with the requirements of this subpart. If the consortium contains one or more CDBG entitlement communities, the consortium must provide for community participation within each CDBG entitlement community, either by the consortium or by the CDBG entitlement community, in a manner sufficient for the CDBG entitlement community to certify that it is following a citizen participation plan.

(3) *Insular Areas.* (i) An insular area must follow the AFH consultation, content, and submission requirements described in this subpart.

(ii) *Community participation.* An insular area shall comply with the citizen participation requirements described in 24 CFR 570.441 if it submits an abbreviated consolidated plan under 24 CFR 91.235. The insular area shall follow the citizen participation requirements of 24 CFR 91.105 and 91.100 (with the exception

of § 91.100(a)(4)), if it submits a complete consolidated plan.

(4) *District of Columbia.* The District of Columbia must follow the requirements applicable to units of general local government described in this subpart.

§ 5.156 Regional assessments and fair housing planning.

(a) *General.* Two or more program participants (regionally collaborating program participants) may, and are encouraged to, collaborate to conduct and submit a single regional AFH to evaluate fair housing issues and determinants from a regional perspective (Regional AFH). The Regional AFH must be prepared in accordance with this subpart. Regionally collaborating program participants need not be contiguous and may cross state boundaries. Regionally collaborating program participants must designate one member as the lead entity to oversee the development and submission of the assessment.

(b) *Coordinating program years and submission deadlines.* To the extent practicable, all regionally collaborating program participants must be on the same program year and fiscal year (as applicable) before submission of the Regional AFH. (See § 5.160; 24 CFR 91.15; and 24 CFR 903.5.) The applicable procedures for changing consolidated plan program participant program year start dates, if necessary, are described in 24 CFR 91.15. The applicable procedures for changing PHA fiscal year beginning dates, if necessary, are described in 24 CFR part 903. If program year and/or fiscal year alignment is not practicable, the submission deadline for a Regional AFH must be based on the designated lead entity's program year start date, or fiscal year beginning date (as applicable). Within 18 months after the date of AFH acceptance, each regionally collaborating program participant that has a program year start date, or fiscal year beginning date, earlier than the designated lead entity must make appropriate revisions or amendments to its consolidated plan, or PHA Plan, to incorporate strategies and proposed actions consistent with the fair housing goals, issues, and other elements identified in the Regional AFH.

(c) *Community participation.* The regionally collaborating program participants must have a plan for community participation that complies with the requirements of this subpart. The community participation process must include citizens, residents, and other interested parties of all regionally collaborating program participants, not just those of the lead entity, and be conducted in a manner sufficient for each collaborating consolidated plan program participant to certify that it is following its applicable citizen participation plan and each collaborating PHA to satisfy the notice and comment requirements in 24 CFR part 903. To the extent that public notice and comment periods differ, the longer period shall apply. A significant revision required of any regionally collaborating program participant will trigger a requirement to revise the Regional AFH.

(d) *Content of the Regional Assessment.* The Regional AFH must include the elements required under § 5.154(d). A Regional AFH does not relieve each regionally collaborating program participant from its obligation to analyze and address local fair housing issues and determinants that affect housing choice within its respective jurisdiction.

§ 5.158 Community participation, consultation, and coordination.

(a) *General.* To ensure that the AFH is informed by meaningful community participation, program participants must give the public reasonable opportunities for involvement in the development of the AFH and in the incorporation of the AFH into the consolidated plan, PHA Plan, and other planning documents as may be applicable. At a minimum, whether preparing an AFH singly or in combination with other program participants, AFH community participation must include the following for consolidated plan program participants and PHAs (as applicable):

(1) *Consolidated plan program participants.* The consolidated plan program participant must follow the policies and procedures described in its applicable citizen participation plan adopted pursuant to 24 CFR part 91 (see 24 CFR 91.105, 91.115, and 91.401) in the process of developing the AFH, obtaining community feedback, and addressing complaints. The jurisdiction must consult with the agencies and organizations identified in consultation requirements at 24 CFR part 91 (see 24 CFR 91.100, 91.110, 91.235, and 91.401).

(2) *PHAs.* PHAs must follow the policies and procedures described in 24 CFR 903.7 and 903.19 in the process of developing the AFH, obtaining community feedback, and addressing complaints.

(b) *Coordination.* A PHA may participate directly with a consolidated plan program participant, prepare its own AFH, or adopt the state's AFH (see 24 CFR 903.15(a)). If the PHA and consolidated plan program participant prepare a single AFH, the program participants will work closely together to provide a forum for consideration of mutual issues affecting fair housing choice and exchange information as necessary to achieve coordination of AFH priorities and goals. The PHA and the consolidated plan program participant must actively participate in AFH community participation consistent with paragraph (a) of this section, and such participation will be in a cohesive manner. The PHA and consolidated plan program participant will exchange information pertaining to housing and community development programs within their respective responsibilities as necessary to assist in developing the AFH.

§ 5.160 AFH submission requirements.

(a) *General.* (1) In order to ensure that fair housing considerations fully inform the consolidated planning and PHA Plan processes and provide accountability to the community, each program participant (including PHAs that choose to prepare their own AFH pursuant to 24 CFR 903.15) shall submit an initial AFH to HUD at least 270 calendar days before the start of the program participant's program year, except that newly eligible jurisdictions under the HOME program shall submit an initial assessment as provided in 24 CFR 92.104.

(2) After acceptance of its initial AFH, each program participant (including PHAs that choose to prepare their own AFH) shall submit subsequent AFHs to HUD at least 195 calendar days before the start of the jurisdiction's program year.

(3) Program participants that participate in a Regional AFH shall submit initial and subsequent assessments as provided in § 5.156(d).

(b) *Late submission.* An accepted AFH, or portion thereof, is a precondition for approval of a consolidated plan (see 24 CFR part 91) and of a PHA Plan (see 24 CFR part 903). If a consolidated plan program participant fails to submit an AFH in a timely manner, HUD may establish a date after AFH acceptance for the jurisdiction to submit its consolidated plan, but in no event past the August 16 deadline provided in 24 CFR 91.15. Failure to submit a consolidated plan by August 16 of the federal fiscal year for which funds are appropriated will automatically result in the loss of the CDBG funds to which the jurisdiction would otherwise be entitled. If a PHA preparing its own AFH fails to submit the AFH in a timely manner, the PHA must submit its AFH no later than 75

calendar days before the commencement of the PHA's fiscal year to avoid any impact on their funding.

(c) *Frequency of submission.* Each consolidated plan program participant must submit an AFH at least once every 5 years, or as such time agreed upon by HUD and the program participant in order to coordinate the AFH submission with time frames used for consolidated plans, cooperation agreements, or other plans. (See 24 CFR 91.15(b)(2).) PHAs participating with their consolidated plan program participants in the AFH process will incorporate the resulting AFH into its PHA Plan every 5 years, and PHAs choosing to undertake their own AFH will further have to update their AFH annually. (See 24 CFR 903.15(b), (c)).

(d) *Coordination of program years and PHA fiscal years.* A consolidated plan program participant or PHA may request to change its program year start date, or fiscal year beginning date, to better coordinate the submission of the AFH, consolidated plan and PHA Plan. For consolidated plan program participants, procedures for changing program years are described in 24 CFR part 91. For PHAs, procedures for changing both program and fiscal years are described in 24 CFR part 903.

§ 5.162 Review of AFH.

(a) *General.* (1) HUD's review of an AFH is to determine whether the program participant has met the requirements for providing its analysis, assessment, and goal setting as set forth in § 5.154(d). The AFH will be deemed accepted 60 calendar days after the date that HUD receives the AFH, unless before that date HUD has provided notification that HUD does not accept the AFH. In its notification, HUD must inform the program participant in writing of the reasons why HUD has not accepted the AFH and the actions that the jurisdiction may take to address these reasons.

(2) HUD's acceptance of an AFH means only that, for purposes of administering HUD program funding, HUD has determined that the program participant has provided the required elements of an AFH as set forth in § 5.154(d). HUD's acceptance does not mean that HUD has determined that a jurisdiction has complied with its obligation to affirmatively further fair housing under the Fair Housing Act; has complied with other provisions of the Act; or has complied with other civil rights laws, regulations or guidance.

(b) *Standard of review.* HUD may choose not to accept an AFH, or a portion of the assessment, if it is inconsistent with fair housing or civil rights laws or if the assessment is substantially incomplete. The following are examples of assessments of fair housing that are substantially incomplete:

(1) An assessment that was developed without the required community participation or the required consultation;

(2) An assessment that fails to satisfy required elements in this part. Failure to include a required element includes an assessment whose priorities or goals are materially inconsistent with the data and other evidence available to the jurisdiction.

(c) *Revisions and resubmission.* The program participant may revise and resubmit the AFH to HUD within 45 calendar days after the date on which HUD provides written notification that it does not accept the AFH. The revised AFH will be deemed accepted after 30 calendar days of the date by which HUD receives the revised AFH, unless before the date HUD has provided notification that HUD does not accept the revised AFH.

§ 5.164 Revising the AFH.

(a) *General*—(1) *Minimum criteria for revising the AFH.* The AFH must be revised under the following circumstances:

(i) Whenever a significant material change in circumstances occurs that calls into question the continued validity of the AFH, such as the program participant is in an area for which the President has declared a disaster under title IV of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*) that is significant, significant demographic changes, significant policy changes (such as significant changes related to zoning, housing plans or policies, or development plans or policies), or significant civil rights findings, determinations, Voluntary Compliance Agreements, or other settlements; or

(ii) Upon HUD's written notification specifying a significant material change that requires the revision.

(2) *Criteria for revising the AFH.* The consolidated plan program participant citizen participation plan adopted pursuant to 24 CFR part 91, PHA Resident Advisory Board requirements pursuant to 24 CFR 903.13, the PHA public comment process pursuant to 24 CFR 903.17, and the PHA amendment or modification process pursuant to 24 CFR 903.21 must specify the criteria that will be used for determining which significant material changes will require revisions to the AFH. Such criteria must include, at a minimum, the circumstances described in paragraph (a)(1) of this section.

(b) *Community participation.* Revisions to an AFH are subject to community participation. The jurisdiction must follow the notice and comment process applicable to consolidated plan substantial amendments under the jurisdiction's citizen participation plan adopted pursuant to 24 CFR part 91 (see 24 CFR 91.105, 91.115, and 91.401). A consortium must follow the participation process applicable to consolidated plan substantial amendments under the consortium's citizen participation plan adopted pursuant to 24 CFR 91.401. Insular areas submitting an abbreviated consolidated plan shall follow the citizen participation requirements of § 570.441. The PHA must follow the notice and comment process applicable to significant amendments or modifications pursuant to 24 CFR 903.13, 903.15, 903.17, and 903.21.

(c) *Submission to HUD.* Upon completion, the revision must be made public and submitted to HUD either at the time of the revision or at the time a consolidated plan substantial amendment must be submitted to HUD pursuant to 24 CFR 91.505(c) or, for PHAs preparing their own AFH pursuant to 24 CFR 903.15(a)(2), at the time a PHA Plan substantial amendment must be submitted to HUD pursuant to 24 CFR 903.23. Letters transmitting copies of revisions must be signed by the official representative of the jurisdiction authorized to take such action. A review by HUD of a revised AFH pursuant will be in accordance with the process provided under § 5.162.

(d) *PHAs.* Upon any revision to the AFH pursuant to this subpart, PHAs must revise their PHA Plan within 18 months pursuant to 24 CFR 903.15(e).

§ 5.166 Recordkeeping.

(a) *General.* Each program participant must establish and maintain sufficient records to enable HUD to determine whether the program participant has met the requirements of this subpart. A PHA not preparing its own AFH in accordance with 24 CFR 903.15(a)(2) must maintain a copy of the applicable AFH and records reflecting actions to affirmatively further fair housing as described in 24 CFR 903.7(o). All program participants shall make these records available for HUD inspection. At a minimum, the following records are needed for each consolidated plan program participant and each PHA that prepares its own AFH:

(1) Information and records relating to the program participant's AFH and any significant revisions to the AFH, including, but not limited to, statistical data, studies, and other diagnostic tools used by the jurisdiction, any policies, procedures, or other documents incorporated by reference into the AFH, and significant material changes that led to a significant revision of the AFH pursuant to § 5.164;

(2) Records demonstrating compliance with the consultation and community participation requirements of this subpart and applicable program regulations, including the names of organizations involved in the development of the AFH, summaries or transcripts of public meeting or hearings, public notices, and other correspondence, distribution lists, surveys, or interviews (as applicable);

(3) Records demonstrating the actions the program participant has taken to affirmatively further fair housing, including activities carried out in furtherance of the assessment; the program participant's AFFH strategy set forth in its AFH, consolidated plan, or PHA Plan; and the actions the program participant has carried out to promote or support the goals identified in § 5.154 during the preceding 5 years;

(4) Where courts or the United States Government have found that the program participant has violated any applicable nondiscrimination and equal opportunity requirements set forth in § 5.105(a) of this subtitle or any applicable civil rights-related program requirement, documentation related to the underlying judicial or administrative finding and affirmative measures that the program participant has taken in response.

(5) Documentation relating to the program participant's efforts to ensure that housing and community development activities (including those assisted under programs administered by HUD) are in compliance with applicable nondiscrimination and equal opportunity requirements set forth in § 5.105(a) of this subtitle and applicable civil rights related program requirements;

(6) Records demonstrating that consortium members, units of general local government receiving allocations from a state, or units of general local government participating in an urban county have conducted their own or contributed to the jurisdiction's assessment (as applicable) and documents demonstrating their actions to affirmatively further fair housing; and

(7) Any other evidence relied upon by the program participant to support its affirmatively furthering fair housing certification.

(b) *Retention period.* All records must be retained for such period as may be specified in the applicable program regulations.

[§§ 5.167–5.180—Reserved]

PART 91—CONSOLIDATED SUBMISSION FOR COMMUNITY PLANNING AND DEVELOPMENT PROGRAMS

■ 3. The authority citation for part 91 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 3601–3619, 5301–5315, 11331–11388, 12701–12711, 12741–12756, and 12901–12912.

■ 4. In § 91.5, the introductory text is revised to read as follows:

§ 91.5 Definitions.

The terms *Affirmatively Furthering Fair Housing, Assessment of Fair Housing or AFH, elderly person,* and *HUD* are defined in 24 CFR part 5.

* * * * *

■ 5. In § 91.100, paragraphs (a)(1), (a)(5), and (c) are revised and paragraph (e) is added to read as follows:

§ 91.100 Consultation; local governments.

(a) *General.* (1) When preparing the AFH and the consolidated plan, the jurisdiction shall consult with other public and private agencies that provide assisted housing, health services, and social services (including those focusing on services to children, elderly persons, persons with disabilities, persons with HIV/AIDS and their families, homeless persons), community- and regionally based organizations that represent protected class members, and organizations that enforce fair housing laws.

* * * * *

(5) The jurisdiction also shall consult with adjacent units of general local government, including local government agencies with metropolitan-wide planning and transportation responsibilities, particularly for problems and solutions that go beyond a single jurisdiction.

* * * * *

(c) *Public housing.* The jurisdiction shall consult with local public housing agencies (PHAs) operating in the jurisdiction regarding consideration of public housing needs, planned programs and activities, the AFH, strategies for affirmatively furthering fair housing, and proposed actions to affirmatively further fair housing in the consolidated plan. (See also 24 CFR 5.158 for coordination when preparing an AFH jointly with a PHA.) This consultation will help provide a better basis for the certification by the authorized official that the PHA Plan is consistent with the consolidated plan and the local government's description of its strategy for affirmatively furthering fair housing and the manner in which it will address the needs of public housing and, where necessary, the manner in which it will provide financial or other assistance to a troubled PHA to improve the PHAs operations and remove the designation of troubled, as well as obtaining PHA input on addressing fair housing issues in public housing and the Housing Choice Voucher Programs. It will also help ensure that activities with regard to affirmatively furthering fair housing, local drug elimination, neighborhood improvement programs, and resident programs and services, funded under a PHA's program and those funded under a program covered by the consolidated plan, are fully coordinated to achieve comprehensive community development goals and affirmatively further fair housing. If a PHA is required to implement remedies under a Voluntary Compliance Agreement, the local jurisdiction should work with or consult with the PHA, as appropriate, to identify actions it may take, if any, to assist the PHA in implementing the required remedies. A local jurisdiction may use CDBG funds for eligible activities or other funds to implement remedies required under a Voluntary Compliance Agreement.

* * * * *

(e) *Affirmatively furthering fair housing.* The jurisdiction shall consult with community and regionally based organizations that represent protected class members, and organizations that enforce fair housing laws, such as State or local fair housing enforcement agencies (including participants in the Fair Housing Assistance Program (FHAP), fair housing organizations, and other nonprofit organizations that receive funding under the Fair Housing Initiative Program (FHIP), and other public and private fair housing service agencies, to the extent that such entities operate within its jurisdiction. This consultation will help provide a better basis for the jurisdiction's AFH, its certification to affirmatively further fair housing and other portions of the consolidated plan concerning affirmatively furthering fair housing. This consultation must occur with any organizations that have the capacity to engage with data informing the AFH and be sufficiently independent and representative to provide meaningful feedback to a jurisdiction on the AFH,

the consolidated plan, and their implementation. A Fair Housing Advisory Council, or similar group, that includes community members and advocates, fair housing experts, housing and community development industry participants, and other key stakeholders is an acceptable method, among others, to meet this consultation requirement. Consultation must occur throughout the fair housing planning process, meaning that, at a minimum, the jurisdiction will consult with the organizations described in this paragraph (e) in the development of both the AFH and the consolidated plan. Consultation on the consolidated plan shall specifically seek input into how the goals identified in an accepted AFH inform the priorities and objectives of the consolidated plan.

■ 6. In § 91.105, paragraphs (a)(1) and (a)(2)(i) through (iii) are revised, paragraph (a)(4) is added, and paragraphs (b), (c), (e)(1), (f), (g), (h), (i), (j) and (l) are revised to read as follows:

§ 91.105 Citizen participation plan; local governments.

(a) *Applicability and adoption of the citizen participation plan.* (1) The jurisdiction is required to adopt a citizen participation plan that sets forth the jurisdiction's policies and procedures for citizen participation. (Where a jurisdiction, before [*effective date of the final rule*], adopted a citizen participation plan but will need to amend the citizen participation plan to comply with provisions of this section, the citizen participation plan shall be amended by [*date to be determined*]).

(2) *Encouragement of citizen participation.* (i) The citizen participation plan must provide for and encourage citizens, residents, and other interested parties to participate in the development of the AFH, any significant revisions to the AFH, the consolidated plan, any substantial amendment to the consolidated plan, and the performance report. These requirements are designed especially to encourage participation by low- and moderate-income persons, particularly those living in slum and blighted areas and in areas where CDBG funds are proposed to be used, and by residents of predominantly low- and moderate-income neighborhoods, as defined by the jurisdiction. A jurisdiction must take appropriate actions to encourage the participation of all its citizens, including minorities and non-English speaking persons, as provided in paragraph (a)(4) of this section, as well as persons with disabilities.

(ii) The jurisdiction shall encourage the participation of local and regional institutions, the Continuum of Care and other organizations (including businesses, developers, nonprofit organizations, philanthropic organizations, and community-based and faith-based organizations) in the process of developing and implementing the AFH and the consolidated plan.

(iii) The jurisdiction shall encourage, in conjunction with consultation with public housing agencies, the participation of residents of public and assisted housing developments (including any resident advisory boards, resident councils, and resident management corporations) in the process of developing and implementing the AFH and the consolidated plan, along with other low-income residents of targeted revitalization areas in which the developments are located. The jurisdictions shall make an effort to provide information to the public housing agency (PHA) about the AFH, AFFH strategy, and consolidated plan activities related to its developments and surrounding communities so that the PHA can make this information available at the annual public hearing(s) required for the PHA Planning process.

* * * * *

(4) The citizen participation plan shall describe the jurisdiction's procedures for assessing its language needs and identify any need for translation of notices and other vital documents. At a minimum, the citizen participation plan shall require that the jurisdiction take reasonable steps to provide language assistance to ensure meaningful access to citizen participation by non-English-speaking persons.

(b) *Development of the AFH and the consolidated plan.* The citizen participation plan must include the following minimum requirements for the development of the AFH and the consolidated plan.

(1)(i) The citizen participation plan must require that, as soon as practical after HUD makes AFH-related data available to the jurisdiction pursuant to 24 CFR 5.154, the jurisdiction will make such information and any other supplemental information the jurisdiction plans to incorporate into its AFH available to the public, public agencies, and other interested parties.

(ii) The citizen participation plan must require that, before the jurisdiction adopts a consolidated plan, the jurisdiction will make available to citizens, public agencies, and other interested parties information that includes the amount of assistance the jurisdiction expects to receive (including grant funds and program income) and the range of activities that may be undertaken, including the estimated amount that will benefit persons of low- and moderate-income. The citizen participation plan also must set forth the jurisdiction's plans to minimize displacement of persons and to assist any persons displaced, specifying the types and levels of assistance the jurisdiction will make available (or require others to make available) to persons displaced, even if the jurisdiction expects no displacement to occur.

(iii) The citizen participation plan must state when and how the jurisdiction will make this information available.

(2) The citizen participation plan must require the jurisdiction to publish the proposed AFH and the proposed consolidated plan in a manner that affords citizens, public agencies, and other interested parties a reasonable opportunity to examine its contents and to submit comments. The citizen participation plan must set forth how the jurisdiction will publish the proposed AFH and the proposed consolidated plan and give reasonable opportunity to examine each document's contents. The requirement for publishing may be met by publishing a summary of each document in one or more newspapers of general circulation, and by making copies of each document available at libraries, government offices, and public places. The summary must describe the contents and purpose of the AFH and/or the consolidated plan (as applicable), and must include a list of the locations where copies of the entire proposed document may be examined. In addition, the jurisdiction must provide a reasonable number of free copies of the plan and/or the assessment (as applicable) to citizens and groups that request it.

(3) The citizen participation plan must provide for at least one public hearing during the development of the AFH and/or the consolidated plan (as applicable). See paragraph (e) of this section for public hearing requirements, generally.

(4) The citizen participation plan must provide a period, not less than 30 days, to receive comments from citizens on the consolidated plan and/or the AFH (as applicable).

(5) The citizen participation plan shall require the jurisdiction to consider any comments or views of citizens received in writing, or orally at the public hearings, in preparing the final AFH and/or the final consolidated plan (as applicable). A summary of these comments or views, and a summary of

any comments or views not accepted and the reasons why, shall be attached to the final AFH and/or the final consolidated plan (as applicable).

(c) *Consolidated plan amendments and AFH revisions.* (1)(i) *Criteria for amendment to consolidated plan.* The citizen participation plan must specify the criteria the jurisdiction will use for determining what changes in the jurisdiction's planned or actual activities constitute a substantial amendment to the consolidated plan. (See § 91.505.) It must include among the criteria for a substantial amendment changes in the use of CDBG funds from one eligible activity to another.

(ii) *Criteria for revision to the AFH.* The jurisdiction must specify the criteria the jurisdiction will use for determining when significant revisions to the AFH will be appropriate. (At a minimum, the specified criteria must include the situations described in 24 CFR 5.164.)

(2) The citizen participation plan must provide citizens with reasonable notice and an opportunity to comment on substantial amendments to the consolidated plan and significant revisions to the AFH. The citizen participation plan must state how reasonable notice and an opportunity to comment will be given. The citizen participation plan must provide a period, not less than 30 days, to receive comments on the substantial amendment or significant revision before the amendment or revision is implemented.

(3) The citizen participation plan shall require the jurisdiction to consider any comments or views of citizens received in writing, or orally at public hearings, if any, in preparing the substantial amendment of the consolidated plan or significant revision to the AFH (as applicable). A summary of these comments or views, and a summary of any comments or views not accepted and the reasons why, shall be attached to the substantial amendment of the consolidated plan or significant revision to the AFH (as applicable).

* * * * *

(e) *Public hearings.* (1)(i) *Consolidated plan.* The citizen participation plan must provide for at least two public hearings per year to obtain citizens' views and to respond to proposals and questions, to be conducted at a minimum of two different stages of the program year. Together, the hearings must address housing and community development needs, development of proposed activities, proposed strategies and actions for affirmatively furthering fair housing consistent with the AFH, and review of program performance.

(ii) To obtain the views of citizens on housing and community development needs, including priority nonhousing community development needs and affirmatively furthering fair housing, the citizen participation plan must provide that at least one of these hearings is held before the proposed consolidated plan is published for comment.

(iii) *Assessment of Fair Housing.* To obtain the views of the community on AFH-related data and affirmatively furthering fair housing in the jurisdiction's housing and community development programs, the citizen participation plan must provide that at least one public hearing is held before the proposed AFH is published for comment.

* * * * *

(f) *Meetings.* The citizen participation plan must provide citizens with reasonable and timely access to local meetings, consistent with accessibility requirements.

(g) *Availability to the public.* The citizen participation plan must provide that the consolidated plan as adopted, substantial amendments, the HUD-accepted AFH, significant revisions, and the performance report will be available to the public, including the availability of materials in a form accessible to persons with disabilities, upon request. The citizen participation plan must state how these documents will be available to the public.

(h) *Access to records.* The citizen participation plan must require the jurisdiction to provide citizens, public agencies, and other interested parties with reasonable and timely access to information and records relating to the jurisdiction's AFH, consolidated plan, and use of assistance under the programs covered by this part during the preceding five years.

(i) *Technical assistance.* The citizen participation plan must provide for technical assistance to groups representative of persons of low- and moderate-income that request such assistance in commenting on the AFH and in developing proposals for funding assistance under any of the programs covered by the consolidated plan, with the level and type of assistance determined by the jurisdiction. The assistance need not include the provision of funds to the groups.

(j) *Complaints.* The citizen participation plan shall describe the jurisdiction's appropriate and practicable procedures to handle complaints from citizens related to the consolidated plan, amendments, the AFH, revisions, and performance reports. At a minimum, the citizen participation plan shall require that the jurisdiction must provide a timely, substantive written response to every written citizen complaint, within an established period of time (within 15 working days, where practicable, if the jurisdiction is a CDBG grant recipient).

* * * * *

(l) *Jurisdiction responsibility.* The requirements for citizen participation do not restrict the responsibility or authority of the jurisdiction for the development and execution of its consolidated plan or AFH.

* * * * *

■ 7. In § 91.110, paragraph (a) is revised to read as follows:

§ 91.110 Consultation; States.

(a) When preparing the AFH and the consolidated plan, the State shall consult with other public and private agencies that provide assisted housing (including any state housing agency administering public housing), health services, and social services (including those focusing on services to children, elderly persons, persons with disabilities, persons with HIV/AIDS and their families, and homeless persons), state- and regionally-based organizations that represent protected class members and organizations that enforce fair housing laws during preparation of the consolidated plan. With respect to public housing:

(1) The State shall consult with any state housing agency administering public housing (PHA) concerning consideration of public housing needs, planned programs and activities, the AFH, strategies for affirmatively furthering fair housing, and proposed actions to affirmatively further fair housing. This consultation will help provide a better basis for the certification by the authorized state official that the PHA Plan is consistent with the consolidated plan and the State's description of its strategy for affirmatively furthering fair housing, and the manner in which it will address the needs of public housing and, where applicable, the manner in which it will provide financial or other assistance to a troubled PHA to improve its operations and remove such designation, as well obtaining PHA input on addressing fair housing issues in public housing and the Housing Choice Voucher programs. It will also help ensure that activities with regard to affirmatively furthering fair housing, local drug elimination, neighborhood improvement programs, and resident programs and services, funded under a PHA's program and those funded under a program covered by the consolidated

plan, are fully coordinated to achieve comprehensive community development goals and affirmatively further fair housing. If a PHA is required to implement remedies under a Voluntary Compliance Agreement, the State should consult with the PHA and identify actions it may take, if any, to assist the PHA in implementing the required remedies.

(2) The State shall consult with state- and regionally-based organizations that represent protected class members, and organizations that enforce fair housing laws, such as state fair housing enforcement agencies (including participants in the Fair Housing Assistance Program (FHAP)), fair housing organizations and other nonprofit organizations that receive funding under the Fair Housing Initiative Program (FHIP), and other public and private fair housing service agencies, to the extent such entities operate within the State. This consultation will help provide a better basis for the State's AFH, its certification to affirmatively further fair housing, and other portions of the consolidated plan concerning affirmatively furthering fair housing. This consultation must occur with any organizations that have the capacity to engage with data informing the AFH and be sufficiently independent and representative to provide meaningful feedback on the AFH, the consolidated plan, and their implementation. A Fair Housing Advisory Council or similar group that includes community members and advocates, fair housing experts, housing and community development industry participants, and other key stakeholders is an acceptable method, among others, to meet this consultation requirement. Consultation must occur throughout the fair housing planning process, meaning that, at a minimum, the jurisdiction will consult with the organizations described in this paragraph (a)(2) in the development of both the AFH and the consolidated plan. Consultation on the consolidated plan shall specifically seek input into how the goals identified in an accepted AFH inform the priorities and objectives of the consolidated plan.

* * * * *

■ 8. In § 91.115, paragraphs (a)(1) and (2) are revised, paragraph (a)(4) is added, and paragraphs, (b), (c), (f), (g), and (h) are revised to read as follows:

§ 91.115 Citizen participation plan; States.

(a) * * *

(1) The State is required to adopt a citizen participation plan that sets forth the State's policies and procedures for citizen participation. (Where a State, before [*effective date of final rule*], adopted a citizen participation plan but will need to amend the citizen participation plan to comply with provisions of this section, the citizen participation plan shall be amended by [*date to be determined*].

(2) *Encouragement of citizen participation.* (i) The citizen participation plan must provide for and encourage citizens, residents, and other interested parties to participate in the development of the AFH, any significant revisions to the AFH, the consolidated plan, any substantial amendments to the consolidated plan, and the performance report. These requirements are designed especially to encourage participation by low- and moderate-income persons, particularly those living in slum and blighted areas and in areas where CDBG funds are proposed to be used and by residents of predominantly low- and moderate-income neighborhoods. A State must take appropriate actions to encourage the participation of all its citizens, including minorities and non-English speaking persons, as provided in paragraph (a)(4) of this section, as well as persons with disabilities.

(ii) The State shall encourage the participation of statewide and regional institutions, Continuums of Care, and other organizations (including businesses, developers, nonprofit organizations, philanthropic organizations, and community and faith-based organizations) that are involved with or affected by the programs or activities covered by the consolidated plan in the process of developing and implementing the AFH and the consolidated plan.

(iii) The State should also explore alternative public involvement techniques that encourage a shared vision of change for the community and the review of program performance, e.g., use of focus groups, and use of Internet.

* * * * *

(4) The citizen participation plan shall describe the State's procedures for assessing its language needs and identify any need for translation of notices and other vital documents. At a minimum, the citizen participation plan shall require the State to make reasonable efforts to provide language assistance to ensure meaningful access to citizen participation by non-English speaking persons.

(b) *Development of the AFH and the consolidated plan.* The citizen participation plan must include the following minimum requirements for the development of the AFH and consolidated plan.

(1)(i) The citizen participation plan must require that, as soon as practical after HUD makes AFH-related data available to the State pursuant to 24 CFR 5.154, the State will make such information and any other supplemental information the State intends to incorporate into its AFH available to the public, public agencies, and other interested parties.

(ii) The citizen participation plan must require that, before the State adopts an AFH or consolidated plan, the State will make available to citizens, public agencies, and other interested parties information that includes the amount of assistance the State expects to receive and the range of activities that may be undertaken, including the estimated amount that will benefit persons of low- and moderate-income and the plans to minimize displacement of persons and to assist any persons displaced. The citizen participation plan must state when and how the State will make this information available.

(2) The citizen participation plan must require the State to publish the proposed AFH and the proposed consolidated plan in a manner that affords citizens, units of general local governments, public agencies, and other interested parties a reasonable opportunity to examine the document's contents and to submit comments. The citizen participation plan must set forth how the State will publish the proposed AFH and the proposed consolidated plan and give reasonable opportunity to examine each document's contents. The requirement for publishing may be met by publishing a summary of the proposed AFH and/or the proposed consolidated plan (as applicable) in one or more newspapers of general circulation, and by making copies of the proposed document(s) available at libraries, government offices, and public places. The summary must describe the contents and purpose of the AFH and/or the consolidated plan (as applicable), and must include a list of the locations where copies of the entire proposed document(s) may be examined. In addition, the State must provide a reasonable number of free copies of the plan and/or the assessment (as applicable) to citizens and groups that request it.

(3) The citizen participation plan must provide for at least one public hearing on housing and community development needs and proposed strategies and actions for affirmatively furthering fair housing consistent with the AFH before the proposed consolidated plan is published for comment. To obtain the public's views on AFH-related data and affirmatively furthering fair housing in the State's housing and community development

programs, the citizen participation plan must provide that at least one public hearing is held before the proposed AFH is published for comment.

(i) The citizen participation plan must state how and when adequate advance notice will be given to citizens of the hearing, with sufficient information published about the subject of the hearing to permit informed comment. (Publishing small print notices in the newspaper a few days before the hearing does not constitute adequate notice. Although HUD is not specifying the length of notice required, it would consider two weeks adequate.)

(ii) The citizen participation plan must provide that the hearing be held at a time and accessible location convenient to potential and actual beneficiaries, and with accommodation for persons with disabilities. The citizen participation plan must specify how it will meet these requirements.

(iii) The citizen participation plan must identify how the needs of non-English speaking residents will be met in the case of a public hearing where a significant number of non-English speaking residents can be reasonably expected to participate.

(4) The citizen participation plan must provide a period, not less than 30 days, to receive comments from citizens and units of general local government on the consolidated plan and/or the AFH (as applicable).

(5) The citizen participation plan shall require the State to consider any comments or views of citizens and units of general received in writing, or orally at the public hearings, in preparing the final AFH and the final consolidated plan. A summary of these comments or views, and a summary of any comments or views not accepted and the reasons therefore, shall be attached to the final AFH and/or the final consolidated plan (as applicable).

(c) *Amendments.* (1)(i) *Criteria for amendment to consolidated plan.* The citizen participation plan must specify the criteria the State will use for determining what changes in the State's planned or actual activities constitute a substantial amendment to the consolidated plan. (See § 91.505.) It must include among the criteria for a substantial amendment changes in the method of distribution of such funds.

(ii) *Criteria for revision to the AFH.* The State must specify the criteria it will use for determining when significant revisions to the AFH will be appropriate. (At a minimum, the specified criteria must include the situations described in 24 CFR 5.164.)

(2) The citizen participation plan must provide citizens and units of general local government with reasonable notice and an opportunity to comment on substantial amendments and significant revisions to the AFH. The citizen participation plan must state how reasonable notice and an opportunity to comment will be given. The citizen participation plan must provide a period, not less than 30 days, to receive comments on the substantial amendment or significant revision before the amendment or revision is implemented.

(3) The citizen participation plan shall require the State to consider any comments or views of citizens and units of general local government received in writing, or orally at public hearings, if any, in preparing the substantial amendment of the consolidated plan or significant revision to the AFH (as applicable). A summary of these comments or views, and a summary of any comments or views not accepted and the reasons why, shall be attached to the substantial amendment of the consolidated plan or significant revision to the AFH (as applicable).

* * * * *

(f) *Availability to the public.* The citizen participation plan must provide that the consolidated plan as adopted, substantial amendments, the HUD-accepted AFH, significant revisions, and the performance report will be available to the public, including the availability of materials in a form accessible to persons with disabilities, upon request. The citizen participation plan must state how these documents will be available to the public.

(g) *Access to records.* The citizen participation plan must require the State to provide citizens, public agencies, and other interested parties with reasonable and timely access to information and records relating to the State's AFH, consolidated plan and use of assistance under the programs covered by this part during the preceding five years.

(h) *Complaints.* The citizen participation plan shall describe the State's appropriate and practicable procedures to handle complaints from citizens related to the consolidated plan, amendments, the AFH, significant revisions and performance report. At a minimum, the citizen participation plan shall require that the State must provide a timely, substantive written response to every written citizen complaint, within an established period of time (within 15 working days, where practicable, if the State is a CDBG grant recipient).

* * * * *

■ 9. In § 91.215, paragraph (a)(5) is added to read as follows:

§ 91.215 Strategic plan.

(a) * * *

(5)(i) Describe how the priorities and specific objectives of the jurisdiction under § 91.215(a)(4) will affirmatively further fair housing by setting forth strategies and actions consistent with the goals and other elements identified in an AFH conducted in accordance with 24 CFR 5.154.

(ii) For issues not addressed by these priorities and objectives, identify additional objectives and priorities for affirmatively furthering fair housing.

* * * * *

■ 10. In § 91.220, paragraph (k) is revised to read as follows:

§ 91.220 Action plan.

* * * * *

(k)(1) *Affirmatively furthering fair housing.* Actions it plans to take during the next year that address fair housing issues identified in the AFH.

(2) *Other actions.* Actions it plans to take during the next year to address obstacles to meeting underserved needs, foster and maintain affordable housing, evaluate and reduce lead-based paint hazards, reduce the number of poverty-level families, develop institutional structure, and enhance coordination between public and private housing and social service agencies (see § 91.215(a), (b), (i), (j), (k), and (l)).

* * * * *

■ 11. In § 91.225, paragraph (a)(1) is revised to read as follows:

§ 91.225 Certifications.

(a) * * *

(1) *Affirmatively furthering fair housing.* Each jurisdiction is required to submit a certification that it will affirmatively further fair housing, which means that it will take meaningful actions to further the goals identified in the AFH conducted in accordance with the requirements of 24 CFR 5.154, and that it will take no action that is materially inconsistent with its obligation to affirmatively further fair housing.

* * * * *

■ 12. Section 91.230 is revised to read as follows:

§ 91.230 Monitoring.

The plan must describe the standards and procedures that the jurisdiction will use to monitor activities carried out in furtherance of the plan, including strategies and actions that address the fair housing issues and goals identified in the AFH, and that the jurisdiction will use to ensure long-term compliance with requirements of the programs involved, including civil rights related program requirements, minority

business outreach and the comprehensive planning requirements.

■ 13. In § 91.235, paragraphs (c)(1) and paragraph (4) are revised to read as follows:

§ 91.235 Special case; abbreviated consolidated plan.

* * * * *

(c) *What is an abbreviated plan?*—(1) Assessment of needs, resources, planned activities. An abbreviated plan must contain sufficient information about needs, resources, and planned activities to address the needs to cover the type and amount of assistance anticipated to be funded by HUD. The plan must describe how the jurisdiction will affirmatively further fair housing by addressing issues identified in an AFH conducted in accordance with 24 CFR 5.154.

* * * * *

(4) *Submissions, Certifications, Amendments, and Performance Reports.* An Insular Area grantee that submits an abbreviated consolidated plan under this section must comply with the submission, certification, amendment, and performance report requirements of 24 CFR 570.440. This includes certification that the grantee will affirmatively further fair housing, which means it will take meaningful actions to further the goals identified in an AFH conducted in accordance with the requirements of 24 CFR 5.154, and that it will take no action that is materially inconsistent with its obligation to affirmatively further fair housing.

* * * * *

■ 14. In § 91.315, paragraph (a)(5) is added to read as follows:

§ 91.315 Strategic plan.

(a) * * *

(5)(i) Describe how the priorities and specific objectives of the State under § 91.315(a)(4) will affirmatively further fair housing by setting forth strategies and actions consistent with the goals and other elements identified in an AFH conducted in accordance with 24 CFR 5.154.

(ii) For issues not addressed by these priorities and objectives, identify additional objectives and priorities for affirmatively furthering fair housing.

* * * * *

■ 15. In § 91.320, paragraph (j) is revised to read as follows:

§ 91.320 Action plan.

* * * * *

(j)(i) *Affirmatively furthering fair housing.* Actions it plans to take during the next year that address fair housing issues identified in the AFH.

(ii) *Other actions.* Actions it plans to take during the next year to implement its strategic plan and address obstacles to meeting underserved needs, foster and maintain affordable housing (including the coordination of Low-Income Housing Tax Credits with the development of affordable housing), evaluate and reduce lead-based paint hazards, reduce the number of poverty level families, develop institutional structure, enhance coordination between public and private housing and social service agencies, address the needs of public housing (including providing financial or other assistance to troubled public housing agencies), and encourage public housing residents to become more involved in management and participate in homeownership.

* * * * *

■ 16. In § 91.325, paragraph (a)(1) is revised to read as follows:

§ 91.325 Certifications.

(a) *General*—(1) *Affirmatively furthering fair housing.* Each State is required to submit a certification that it will affirmatively further fair housing, which means that it will take meaningful actions to further the goals identified in an AFH conducted in accordance with the requirements of 24 CFR 5.154, and that it will take no action that is materially inconsistent with its obligation to affirmatively further fair housing.

* * * * *

■ 17. Section 91.415 is revised to read as follows:

§ 91.415 Strategic plan.

Strategies and priority needs must be described in the consolidated plan in accordance with the provisions of § 91.215 for the entire consortium. The consortium is not required to submit a nonhousing Community Development Plan; however, if the consortium includes CDBG entitlement communities, the consolidated plan must include the nonhousing Community Development Plans of the CDBG entitlement community members of the consortium. The consortium must set forth its priorities for allocating housing (including CDBG and ESG, where applicable) resources geographically within the consortium, describing how the consolidated plan will address the needs identified (in accordance with § 91.405), setting forth strategies and actions consistent with the goals and other elements identified in an AFH conducted in accordance with 24 CFR 5.154, describing the reasons for the consortium's allocation priorities, and identifying any obstacles there are to addressing underserved needs.

■ 18. In § 91.420, paragraph (b) is revised to read as follows:

§ 91.420 Action plan.

* * * * *

(b) *Description of resources and activities.* The action plan must describe the resources to be used and activities to be undertaken to pursue its strategic plan, including actions it plans to take during the next year that address fair housing issues identified in the AFH. The consolidated plan must provide this description for all resources and activities within the entire consortium as a whole, as well as a description for each individual community that is a member of the consortium.

* * * * *

■ 19. In § 91.425, paragraph (a)(1)(i) is revised to read as follows:

§ 91.425 Certifications.

(a) *Consortium certifications*—(1) *General*—(i) *Affirmatively furthering fair housing.* Each consortium must certify that it will affirmatively further fair housing, which means that it will take meaningful actions to further the goals identified in an AFH conducted in accordance with the requirements of 24 CFR 5.154, and that it will take no action that is materially inconsistent with its obligation to affirmatively further fair housing.

* * * * *

■ 20. In § 91.505, add paragraph (d) to read as follows:

§ 91.505 Amendments to the consolidated plan.

* * * * *

(d) The jurisdiction must ensure that amendments to the plan are consistent with its certification to affirmatively further fair housing and the analysis and strategies of the AFH.

* * * * *

PART 92—HOME INVESTMENT PARTNERSHIPS PROGRAM

■ 21. The authority citation for part 92 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 12701–12839.

■ 22. Revise § 92.104 to read as follows:

§ 92.104 Submission of a consolidated plan and Assessment of Fair Housing.

A jurisdiction that has not submitted a consolidated plan to HUD must submit to HUD, not later than 90 days after providing notification under § 92.103, a consolidated plan in accordance with 24 CFR part 91 and an Assessment of Fair Housing in

accordance with 24 CFR part 5, subpart A.

■ 23. In § 92.508, revise paragraph (a)(7)(i)(C) to read as follows:

§ 92.508 Recordkeeping.

(a). * * *

(7) * * *

(i) * * *

(C) Documentation of the actions the participating jurisdiction has taken to affirmatively further fair housing, including documentation related to the participating jurisdiction's Assessment of Fair Housing as described in 24 CFR part 5, subpart A.

* * * * *

PART 570—COMMUNITY DEVELOPMENT BLOCK GRANTS

■ 24. The authority citation for part 570 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 5300–5320.

■ 25. In § 570.3, revise the introductory text to read as follows:

§ 570.3 Definitions.

The terms *Affirmatively Furthering Fair Housing, Assessment of Fair Housing or AFH, HUD,* and *Secretary* are defined in 24 CFR part 5. All of the following definitions in this section that rely on data from the United States Bureau of the Census shall rely upon the data available from the latest decennial census.

* * * * *

■ 26. In § 570.205, paragraph (a)(4)(vii) is revised to read as follows:

§ 570.205 Eligible planning, urban environmental design and policy-planning-management-capacity building activities.

(a) * * *

(4) * * *

(vii) Assessment of Fair Housing.

* * * * *

■ 27. In § 570.441, paragraphs (b) introductory text and (b)(1) introductory text, and paragraphs (b)(2), (b)(3), (b)(4), (c), (d), and (e) are revised to read as follows:

§ 570.441 Citizen participation—insular areas.

* * * * *

(b) *Citizen participation plan.* The insular area jurisdiction must develop and follow a detailed citizen participation plan and must make the plan public. The plan must be completed and available before the AFH and statement for assistance is submitted to HUD, and the jurisdiction must certify that it is following the plan. The plan must set forth the jurisdiction's policies and procedures for:

(1) Giving citizens, residents, and other interested parties timely notice of local meetings and reasonable and timely access to local meetings consistent with accessibility requirements, as well as information, and records relating to the grantee's proposed and actual use of CDBG funds including, but not limited to:

* * * * *

(2) Providing technical assistance to groups that are representative of persons of low- and moderate-income that request assistance in commenting on the Assessment of Fair Housing (AFH) and developing proposals. The level and type of assistance to be provided is at the discretion of the jurisdiction. The assistance need not include the provision of funds to the groups;

(3) Holding a minimum of two public hearings for the purpose of obtaining citizens' views and formulating or responding to proposals and questions. Each public hearing must be conducted at a different stage of the CDBG program year. Together, the hearings must address affirmatively furthering fair housing, community development and housing needs, development of proposed activities, proposed strategies and actions for affirmatively furthering fair housing consistent with the AFH, and review of program performance. There must be reasonable notice of the hearings, and the hearings must be held at times and accessible locations convenient to potential or actual beneficiaries, with reasonable accommodations including material in accessible formats for persons with disabilities. The jurisdiction must specify in its citizen participation plan how it will meet the requirement for hearings at times and accessible locations convenient to potential or actual beneficiaries;

(4) Assessing its language needs, identifying any need for translation of notices and other vital documents and, in the case of public hearings, meeting the needs of non-English speaking residents where a significant number of non-English speaking residents can reasonably be expected to participate. At a minimum, the citizen participation plan shall require the jurisdiction to make reasonable efforts to provide language assistance to ensure meaningful access to citizen participation by non-English speaking persons;

* * * * *

(c) *Publication of proposed AFH and proposed statement.* (1) The insular area jurisdiction shall publish a proposed AFH and a proposed statement consisting of the proposed community development activities and community development objectives (as applicable) in order to afford affected citizens an opportunity to:

(i) Examine the document's contents to determine the degree to which they may be affected;

(ii) Submit comments on the proposed document; and

(iii) Submit comments on the performance of the jurisdiction.

(2) The requirement for publishing in paragraph (c)(1) of this section may be met by publishing a summary of the proposed document in one or more newspapers of general circulation and by making copies of the proposed document available at libraries, government offices, and public places. The summary must describe the contents and purpose of the proposed document and must include a list of the locations where copies of the entire proposed document may be examined.

(d) *Preparation of the AFH and final statement.* An insular area jurisdiction must prepare an AFH and a final statement. In the preparation of the AFH and final statement, the jurisdiction shall consider comments and views received relating to the proposed document and may, if appropriate, modify the final document. The final AFH and final statement shall be made available to the public. The final statement shall include the community development objectives, projected use of funds, and the community development activities.

(e) *Program amendments.* To assure citizen participation on program amendments to final statements and significant revisions to AFHs, the insular area grantee shall:

(1) Furnish citizens information concerning the amendment or significant revision (as applicable);

(2) Hold one or more public hearings to obtain the views of citizens on the proposed amendment or significant revision;

(3) Develop and publish the proposed amendment or significant revision in such a manner as to afford affected citizens an opportunity to examine the contents, and to submit comments on the proposed amendment or significant revision;

(4) Consider any comments and views expressed by citizens on the proposed amendment or significant revision and, if the grantee finds it appropriate, make modifications accordingly; and

(5) Make the final amendment to the community development program or significant revision to the AFH available to the public before its submission to HUD.

* * * * *

■ 28. In § 570.480, paragraph (c) is revised to read as follows:

§ 570.480 General.

* * * * *

(c) In exercising the Secretary's responsibility to review a State's performance, the Secretary will give maximum feasible deference to the State's interpretation of the statutory requirements and the requirements of this regulation, provided that these interpretations are not plainly inconsistent with the Act and the Secretary's enforcement responsibilities to achieve compliance with the intent of the Congress as declared in the Act. The Secretary will not determine that a State has failed to carry out its certifications in compliance with requirements of the Act (and this regulation) unless the Secretary finds that procedures and requirements adopted by the State are insufficient to afford reasonable assurance that activities undertaken by units of general local government were not plainly inappropriate to meeting the primary objectives of the Act, this regulation, the State's community development objectives, and the State's responsibility to affirmatively further fair housing (see § 570.487(b)).

* * * * *

■ 29. In § 570.486, paragraphs (a)(2), (a)(4), and (a)(5) are revised to read as follows:

§ 570.486 Local government requirements.

(a) * * *

(2) Ensure that citizens will be given reasonable and timely access to local meetings consistent with accessibility requirements, as well as information and records relating to the unit of local government's proposed and actual use of CDBG funds;

* * * * *

(4) Provide technical assistance to groups representative of persons of low and moderate income that request assistance in developing proposals (including proposed strategies and actions to affirmatively further fair housing) in accordance with the procedures developed by the State. Such assistance need not include providing funds to such groups;

(5) Provide for a minimum of two public hearings, each at a different stage of the program, for the purpose of obtaining citizens' views and responding to proposals and questions. Together the hearings must cover community development and housing needs (including affirmatively furthering fair housing), development of proposed activities and a review of program performance. The public hearings to cover community development and housing needs must be held before submission of an application to the State. There must be reasonable notice of the hearings and they must be held at times and accessible locations convenient to potential or actual beneficiaries, with accommodations for persons with disabilities. Public hearings shall be conducted in a manner to meet the needs of non-English speaking residents where a significant number of non-English speaking residents can reasonably be expected to participate;

* * * * *

■ 30. In § 570.487, paragraph (b) is revised to read as follows:

§ 570.487 Other applicable laws and related program requirements.

* * * * *

(b) *Affirmatively furthering fair housing.* The Act requires the State to certify to the satisfaction of HUD that it will affirmatively further fair housing. The Act also requires each unit of general local government to certify that it will affirmatively further fair housing. The certification that the State will affirmatively further fair housing shall specifically require the State to assume the responsibility of fair housing planning by:

(1) Taking meaningful actions to further the goals identified in an AFH conducted in accordance with the requirements of 24 CFR 5.154;

(2) Not taking actions that are materially inconsistent with its obligation to affirmatively further fair housing (see 24 CFR 5.150); and

(3) Assuring that units of local government funded by the State comply with their certifications to affirmatively further fair housing; and

(4) Assuring that units of local government funded by the State comply with their certifications to affirmatively further fair housing.

* * * * *

■ 31. In § 570.490, paragraph (a)(1) and paragraph (b) are revised to read as follows:

§ 570.490 Recordkeeping requirements.

(a) *State records.* (1) The State shall establish and maintain such records as may be necessary to facilitate review and audit by HUD of the State's administration of CDBG funds under § 570.493. The content of records maintained by the State shall be as jointly agreed upon by HUD and the States and sufficient to enable HUD to make the determinations described at § 570.493. For fair housing and equal opportunity purposes, and as applicable, such records shall include documentation related to the State's AFH, as described in 24 CFR part 5, subpart A. The records shall also permit audit of the States in accordance with 24 CFR part 85.

* * * * *

(b) *Unit of general local government's record.* The State shall establish recordkeeping requirements for units of general local government receiving CDBG funds that are sufficient to facilitate reviews and audits of such units of general local government under §§ 570.492 and 570.493. For fair housing and equal opportunity purposes, and as applicable, such records shall include documentation related to the State's AFH as described in 24 CFR part 5, subpart A.

* * * * *

■ 32. In § 570.506, paragraph (g)(1) is revised to read as follows:

§ 570.506 Records to be maintained.

* * * * *

(g) * * *

(1) Documentation related to the recipient's AFH, as described in 24 CFR part 5, subpart A.

* * * * *

■ 33. In § 570.601, paragraph (a)(2) is revised to read as follows:

§ 570.601 Public Law 88–352 and Public Law 90–284; affirmatively furthering fair housing; Executive Order 11063.

(a) * * *

(2) Public Law 90–284, which is the Fair Housing Act (42 U.S.C. 3601–3620). In accordance with the Fair Housing Act, the Secretary requires that grantees administer all programs and activities related to housing and community development in a manner to affirmatively further the policies of the Fair Housing Act. Furthermore, in accordance with section 104(b)(2) of the Act, for each community receiving a grant under subpart D of this part, the certification that the grantee will affirmatively further fair housing shall specifically require the grantee to take meaningful actions to further the goals identified in an AFH conducted in accordance with the requirements of 24 CFR 5.154 and take no action that is materially inconsistent with its obligation to affirmatively further fair housing (see 24 CFR 5.150).

* * * * *

■ 34. In § 570.904, paragraph (a)(1) introductory text, paragraph (a)(2), and paragraph (c) are revised to read as follows:

§ 570.904 Equal opportunity and fair housing review criteria.

(a) *General.* (1) Where the criteria in paragraphs (b), (c), and (d) of this section are met, the Department will

presume that the recipient has carried out its CDBG-funded program in accordance with civil rights certifications and civil rights requirements of the Act relating to equal employment opportunity, equal opportunity in services, benefits and participation, and is affirmatively furthering fair housing unless:

* * * * *

(2) In such instances, or where the review criteria in paragraphs (b), (c), and (d) of this section are not met, the recipient will be afforded an opportunity to present evidence that it has not failed to carry out the civil rights certifications and fair housing requirements of the Act. The Secretary's determination of whether there has been compliance with the applicable requirements will be made based on a review of the recipient's performance, evidence submitted by the recipient, and all other available evidence. The Department may also initiate separate compliance reviews under title VI of the Civil Rights Act of 1964 or section 109 of the Act.

* * * * *

(c) *Review for fair housing.* (1) See the requirements in the Fair Housing Act (42 U.S.C. 3601–20), as well as § 570.601(a).

(2) *Affirmatively furthering fair housing.* The Department will review a recipient's performance to determine if it has administered all programs and activities related to housing and community development in accordance with § 570.601(a)(2), which sets forth the grantee's responsibility to affirmatively further fair housing.

* * * * *

PART 574—HOUSING OPPORTUNITIES FOR PERSONS WITH AIDS

■ 35. The authority citation for part 574 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 12901–12912.

■ 36. Section 574.530 is revised to read as follows:

§ 574.530 Recordkeeping.

Each grantee must ensure that records are maintained for a four-year period to document compliance with the provisions of this part. Grantees must maintain the following:

(a) Current and accurate data on the race and ethnicity of program participants.

(b) Documentation related to the formula grantee's Assessment of Fair Housing, as described in 24 CFR part 5, subpart A.

PART 576—EMERGENCY SOLUTIONS GRANTS PROGRAM

■ 37. The authority citation for part 576 continues to read as follows:

Authority: 42 U.S.C. 11371 *et seq.,* 42 U.S.C. 3535(d).

■ 38. In § 576.500, add paragraph (s)(5) to read as follows:

§ 576.500 Recordkeeping and reporting requirements.

* * * * *

(s) * * *

(5) Documentation related to the recipient's Assessment of Fair Housing as described in 24 CFR part 5, subpart A.

* * * * *

PART 903—PUBLIC HOUSING AGENCY PLANS

■ 39. The authority citation for part 903 continues to read as follows:

Authority: 42 U.S.C. 1437c; 42 U.S.C. 3535(d).

■ 40. Section 903.2 is revised by adding paragraph (a)(3) and revising paragraphs (d)(2) and (3) to read as follows:

§ 903.2 With respect to admissions, what must a PHA do to deconcentrate poverty in its developments and comply with fair housing requirements?

(a) * * *

(3) In accordance with the PHA's obligation to affirmatively further fair housing, the PHA's policies that govern its ''development related activities'' including affirmative marketing; tenant selection and assignment policies; applicant consultation and information; provision of additional supportive services and amenities; as well as construction, rehabilitation, modernization, demolition, disposition, designation, or physical accessibility of its housing and other facilities under its PHA Plan should be designed to reduce racial and national origin concentrations, including racially or ethnically concentrated areas of poverty, and to reduce segregation and promote integration, reduce disparities in access to community assets, and address disproportionate housing needs by protected class. Any affirmative steps or incentives a PHA Plans to take must be stated in the admission policy and be consistent with the applicable Assessment of Fair Housing conducted in accordance with the requirements of 24 CFR 5.150 through 24 CFR 5.166.

* * * * *

(d) * * *

(2) *Affirmatively Furthering Fair Housing.* PHA policies that govern eligibility, selection and admissions under its PHA Plan must be designed to reduce the concentration of tenants and other assisted persons by race, national origin, and disability in conformity with any applicable Assessment of Fair Housing as defined at 24 CFR 5.150–5.166 and the PHA's assessment of its fair housing needs as defined in this part at § 903.7(o). Any affirmative steps or incentives a PHA plans to take must be stated in the admission policy. Any PHA plans for the construction, rehabilitation, modernization, demolition, disposition, designation, or physical accessibility of its housing and other facilities must be stated in the appropriate Capital Fund and 5-Year Plan as required by HUD and must be consistent with the applicable Assessment of Fair Housing.

(i) HUD regulations provide that PHAs must take affirmative steps to overcome the effects of discrimination and should take affirmative steps to overcome the effects of conditions which resulted in limiting participation of persons because of their race, national origin, disability, or other prohibited basis (24 CFR 1.4(b)(6)).

(ii) Such affirmative steps may include but are not limited to, appropriate affirmative marketing efforts; use of tenant selection and assignment policies that lead to desegregation (e.g., use of minimum/ceiling rents, narrowly tailored site-based waiting lists and residency preferences such as those designed to assist in deinstitutionalizing individuals with disabilities); additional applicant consultation and information; and provision of additional supportive services and amenities to a development (such as supportive services that enable an individual with a disability to transfer from an institutional setting into the community).

(3) *Validity of certification.* (i) A PHA's certification under § 903.7(o) will be subject to challenge where it appears that a PHA Plan or its implementation:

(A) Does not reduce racial and national origin concentration in developments or buildings and is perpetuating segregated housing;

(B) Is creating new segregation in housing; or

(C) Fails to meet the affirmatively furthering fair housing requirements at 24 CFR 5.150 through 5.166.

(ii) If HUD challenges the validity of a PHA's certification, the PHA must establish that it is providing a full range of housing opportunities to applicants and tenants or that it is implementing actions described in paragraph (d)(2)(ii) of this section.

* * * * *

■ 41. In § 903.7, paragraph (o) is revised to read as follows:

§ 903.7 What information must a PHA provide in the Annual Plan?

* * * * *

(o) *Civil rights certification.* (1) The PHA must certify that it will carry out its plan in conformity with title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d–2000d–4), the Fair Housing Act (42 U.S.C. 3601–19), section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), and title II of the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*). The PHA is required to submit a certification that it will affirmatively further fair housing, which means that it will take meaningful actions to further the goals identified in the AFH conducted in accordance with the requirements of 24 CFR 5.154, that will take no action that is materially inconsistent with its obligation to affirmatively further fair housing, and that it will address fair housing issues and determinants in its programs in accordance with paragraph (o)(3) of this section.

(2) The certification is applicable to both the 5-Year Plan and the Annual Plan, including any plan incorporated therein, including but not limited to tenant and participant selection, occupancy, and capital activities.

(3) A PHA shall be considered in compliance with the certification requirement to affirmatively further fair housing if the PHA fulfills the requirements of § 903.2(d) and:

(i) Examines its programs or proposed programs;

(ii) Identifies any fair housing issues and determinants within those programs;

(iii) Addresses those issues and determinants in a reasonable fashion in view of the resources available;

(iv) Works with jurisdictions to implement any of the jurisdiction's initiatives to affirmatively further fair housing that require the PHA's involvement;

(v) Operates programs in a manner consistent with any applicable consolidated plan under 24 CFR part 91 and with any order or agreement to comply with the authorities specified in paragraph (o)(1) of this section;

(vi) Complies with any contribution or consultation requirement with respect to any applicable AFH under 24 CFR 5.150–5.166; and

(vii) Maintains records reflecting these analyses, actions, and the results of these actions.

* * * * *

■ 42. Section 903.15 is revised to read as follows:

§ 903.15 What is the relationship of the public housing agency plans to the Consolidated Plan and the Assessment of Fair Housing?

(a) The preparation of an Assessment of Fair Housing (AFH) is required in accordance with 24 CFR 5.154–5.166. The PHA, as appropriate, has three options in meeting its AFH requirements. The PHA must notify HUD 60 days before its certification is due of the option it chooses. The options are:

(1) *Option 1.* The PHA may participate with its unit of general local government and ensure that the PHA Plan is consistent with the applicable Consolidated Plan and AFH for the unit of general local government in which the PHA is located. For purposes of determining the applicable Consolidated Plan and AFH, the PHA will use the unit of general local government where 60 percent of the PHA's projects (counting hard units) are located. However, if the majority is closer to 50 percent, the PHA may choose the unit of general local government that more closely aligns to its planning activities under this part 903 and 24 CFR part 905. For PHAs with only Section 8 tenant-based assistance, the PHA must the coordinate with the jurisdiction that governs the PHA's operation (e.g., where the Mayor appoints the Board that hires the Executive Director). The PHA must submit a certification by the appropriate officials that the PHA Plan is consistent with the applicable Consolidated Plan and AFH. (See also 24 CFR 5.158 for coordination when preparing an AFH jointly with a jurisdiction.)

(2) *Option 2.* The PHA may conduct its own AFH with geographic scope and proposed actions scaled to the PHA's operations. The PHA would certify that its PHA Plan is consistent with the AFH and is required to submit a certification that it will affirmatively further fair housing, which means that it will take meaningful actions to further the goals identified in the AFH conducted in accordance with the requirements of 24 CFR 5.154, and that it will take no action that is materially inconsistent with its obligation to affirmatively further fair housing.

(3) *Option 3.* For PHAs that are covered by state agencies, the applicable Consolidated Plan and AFH are the State's Consolidated Plan and AFH. The PHA may choose whether to participate or not with the State in the preparation of the state agency's AFH but will be bound either way by the state agency conclusions contained in the State's AFH. These PHAs must demonstrate that their development related activities affirmatively further fair housing and must submit a certification by the appropriate officials that the PHA Plan is consistent with the applicable Consolidated Plan and AFH.

(b) PHAs may request to change their fiscal years to better coordinate their planning with the planning done under the Consolidated Plan process, by State or local officials, as applicable.

(c) If the PHA selects Option 2, it must update its own AFH every year. PHAs that select Option 1 are required to participate in the AFH process every 5 years. PHAs that select Option 3 are required to incorporate their State's Consolidated Plan and AFH once every 5 years.

(d) PHAs may select one of the three options, unless their obligations are prescribed in a binding agreement with HUD such as a Recovery Agreement or Voluntary Compliance Agreement which may incorporate the corrective actions that would require alternative AFH procedures such as that the PHA must participate in their unit of local government's AFH.

(e) If a significant change necessitates a PHA Plan amendment, the PHA will have up to 18 months to make this change to its PHA 5-Year Plan in accordance with the provisions of § 903.21.

■ 43. In § 903.23, paragraph (f) is added to read as follows:

§ 903.23 What is the process by which HUD reviews, approves, or disapproves an Annual Plan?

* * * * *

(f) *Recordkeeping.* PHAs must maintain a copy of the Assessment of Fair Housing as described in 24 CFR part 5, subpart A and records reflecting actions to affirmatively further fair housing as described in § 903.7(o).

Dated: June 25, 2013.

Shaun Donovan,

Secretary.

[FR Doc. 2013–16751 Filed 7–18–13; 8:45 am]

BILLING CODE 4210–67–P

FEDERAL REGISTER

Vol. 78 Friday,
No. 139 July 19, 2013

Part V

The President

Federal Register
Vol. 78, No. 139
Friday, July 19, 2013

Presidential Documents

Title 3—

The President

Memorandum of July 15, 2013

Expanding National Service Through Partnerships to Advance Government Priorities

Memorandum for the Heads of Executive Departments and Agencies

Service has always been integral to the American identity. Our country was built on the belief that all of us, working together, can make this country a better place for all. That spirit remains as strong and integral to our identity today as at our country's founding.

Since its creation 20 years ago, the Corporation for National and Community Service (CNCS) has been the Federal agency charged with leading and expanding national service. The Edward M. Kennedy Serve America Act of 2009 (SAA) expanded CNCS's authority to create opportunities for more Americans to serve. This landmark, bipartisan legislation focuses national service on six areas: emergency and disaster services; economic opportunity; education; environmental stewardship; healthy futures; and veterans and military families. The SAA provides greater opportunities for CNCS to partner with other executive departments and agencies (agencies) and with the private sector to utilize national service to address these critical areas.

National service and volunteering can be effective solutions to national challenges and can have positive and lasting impacts that reach beyond the immediate service experience. Americans engaged in national service make an intensive commitment to tackle unmet national and local needs by working through non-profit, faith-based, and community organizations. Service can help Americans gain valuable skills, pursue higher education, and jumpstart their careers, which can provide immediate and long-term benefits to those individuals, as well as the communities in which they serve.

Americans are ready and willing to serve. Applications from Americans seeking to engage in national service programs far exceed the number of available positions. By creating new partnerships between agencies and CNCS that expand national service opportunities in areas aligned with agency missions, we can utilize the American spirit of service to improve lives and communities, expand economic and educational opportunities, enhance agencies' capacity to achieve their missions, efficiently use tax dollars, help individuals develop skills that will enable them to prepare for long-term careers, and build a pipeline to employment inside and outside the Federal Government.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to expand the positive impact of national service, I hereby direct the following:

Section 1. *Establishing a Task Force on Expanding National Service.* There is established a Task Force on Expanding National Service, to be co-chaired by the Chief Executive Officer of CNCS and the Director of the Domestic Policy Council, which shall include representatives from agencies and offices that administer programs and develop policies in areas that include the six focus areas set forth in the SAA. The Task Force shall include representatives from:

(a) the Department of Defense;

(b) the Department of Justice;

(c) the Department of the Interior;

(d) the Department of Agriculture;

(e) the Department of Commerce;

(f) the Department of Labor;

(g) the Department of Health and Human Services;

(h) the Department of Housing and Urban Development;

(i) the Department of Transportation;

(j) the Department of Energy;

(k) the Department of Education;

(l) the Department of Veterans Affairs;

(m) the Department of Homeland Security;

(n) the Peace Corps;

(o) the National Science Foundation;

(p) the Office of Personnel Management;

(q) the Environmental Protection Agency;

(r) the White House Office of Cabinet Affairs; and

(s) such other agencies and offices as the co-chairs may designate.

Sec. 2. *Mission and Function of the Task Force.* (a) The Task Force shall:

(i) identify existing, and, if appropriate, recommend new, policies or practices that support the expansion of national service and volunteer opportunities that align with the SAA and agency priorities;

(ii) make recommendations on the most effective way to coordinate national service and volunteering programs across the Federal Government;

(iii) identify and develop opportunities for interagency agreements between CNCS and other agencies to support the expansion of national service and volunteering;

(iv) identify and develop public-private partnerships to support the expansion of national service and volunteering;

(v) identify and develop strategies to use innovation and technology to facilitate the ability of the public to participate in national service and volunteering activities; and

(vi) develop a mechanism to evaluate the effectiveness and cost-effectiveness of national service and volunteering interventions in achieving agency priorities, and aggregate and disseminate the results of that evaluation.

(b) Within 18 months of the date of this memorandum, the Task Force shall provide the President with a report on the progress made with respect to the functions set forth in subsection (a) of this section.

Sec. 3. *Facilitating National Service and Volunteering Partnerships.* (a) Each agency on the Task Force shall:

(i) within 180 days of the date of this memorandum, consult with CNCS about how existing authorities and CNCS programs can be used to enter into interagency and public-private partnerships that allow for meaningful national service and volunteering opportunities, including participating in AmeriCorps, and help the agency achieve its mission;

(ii) work with CNCS to evaluate the effectiveness and cost-effectiveness of such partnerships; and

(iii) work with CNCS to identify ways in which the agency's national service participants and volunteers can develop transferable skills, and also how national service can serve as a pipeline to employment inside and outside the Federal Government.

(b) Where practicable, agencies may consider entering into interagency agreements with CNCS to share program development and funding responsibilities, as authorized under 42 U.S.C. 12571(b)(1).

Sec. 4. *Recruitment of National Service Participants in the Civilian Career Services.* In order to provide national service participants a means to pursue additional opportunities to continue their public service through career civilian service, the Office of Personnel Management shall, within 120 days of the date of this memorandum, issue guidance to agencies on developing and improving Federal recruitment strategies for participants in national service.

Sec. 5. *General Provisions.* (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law or Executive Order to an agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Chief Executive Officer of CNCS is hereby authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, July 15, 2013.

[FR Doc. 2013–17602
Filed 7–18–13; 11:15 am]
Billing code 6050–28–P

Presidential Documents

Notice of July 17, 2013

Continuation of the National Emergency With Respect to the Former Liberian Regime of Charles Taylor

On July 22, 2004, by Executive Order 13348, the President declared a national emergency with respect to the former Liberian regime of Charles Taylor pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the foreign policy of the United States constituted by the actions and policies of former Liberian President Charles Taylor and other persons, in particular their unlawful depletion of Liberian resources and their removal from Liberia and secreting of Liberian funds and property, which have undermined Liberia's transition to democracy and the orderly development of its political, administrative, and economic institutions and resources.

Although Liberia has made significant advances to promote democracy, and the Special Court for Sierra Leone convicted Charles Taylor for war crimes and crimes against humanity, the actions and policies of Charles Taylor and others have left a legacy of destruction that could still challenge Liberia's transformation and recovery. The actions and policies of these persons continue to pose an unusual and extraordinary threat to the foreign policy of the United States. For this reason, the national emergency declared on July 22, 2004, and the measures adopted on that date to deal with that emergency, must continue in effect beyond July 22, 2013. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13348.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,

July 17, 2013.

[FR Doc. 2013–17605

Filed 7–18–13; 11:15 am]

Billing code 3295–F3

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Federal Register

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Friday, July 19, 2013

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